

ANNEX F

**REPLIES BY THE PARTIES TO QUESTIONS POSED BY THE PANEL
 IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
 AND COMMENTS BY THE PARTIES ON THE OTHER PARTIES' REPLIES**

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ANNEX F-1

**REPLIES BY THE UNITED STATES TO QUESTIONS POSED BY THE PANEL
IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
7 MARCH 2005**

For all parties:

119. With reference to exhibit US-123 (reproduced at para. 9 of attachment II of the US rebuttal), do the references in ISPM 11 to "indirectly affect plants ... by other processes such as competition" (page 34) and "significant reduction, displacement, or elimination of other plant species" (page 19) support the view that the term "injurious" in the IPPC definition of "pest" ("any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products") should be given a broad interpretation?

1. The cited language makes clear that the definition is to be interpreted to include all reasonably foreseeable injuries that an organism might cause to plant life or health. Also relevant in this regard is the discussion in Annex 1 of ISPM 11, which explicitly provides that the scope of the IPPC also extends to those injuries caused by organisms that indirectly affect plant species or health, through effects on other organisms in the ecosystem. The discussion in Annex I thus directly contradicts many of the artificial distinctions the EC has previously suggested.

120. With reference to Annex A(1)(d) of the SPS Agreement, please answer the following questions:

- (a) **What is the meaning of the term "other damage"?**
- (b) **Does the term "other" imply that Annex A(1)(a) through (c) are also about "damage"? If so, does the term "other damage" cover damage sustained by plants, animals or humans other than damage to their "life or health"? Please provide examples.**
- (c) **Is "other damage" limited to damage sustained by plants, animals or humans? If not, please provide examples.**

2. *Subpart (a):* The meaning of the term "other damage" in Annex A(1)(d) is indicated by its context: in particular, the meaning of this term is indicated by the fact that the term "other damage" is used at the end of a list in Annex A(1) of different types of risks of damage "arising from the entry, establishment, or spread of pests." Paragraph A(1)(a) specifies that the SPS Agreement addresses damage to "animal or plant life or health" arising from the "entry, establishment or spread of pests," and Paragraph A(1)(c) specifies that the SPS Agreement addresses damage to "human life or health" arising from the "entry, establishment or spread of pests." Thus, in context, the term "other damage" must mean damage other than damage to "animal or plant life or health" or "human life or health."

3. *Subpart (b) and (c):* As discussed in the answer to *subpart (a)* above, the use of the term "other" in Annex A(1)(d) does imply that Annex A(1)(a) through (c) are also about "damage," and the term "other damage" should be construed to address damage other than damage to the life and health of plants, animals or humans. The damage could, but would not necessarily, be to plants, animals or humans, and could include, for example, property damage from pests. Nothing in the phrase "other

damage" limits that term to property damage, and nothing in this phrase *excludes* non-life or non-health damage to plants, animals or humans caused by pests.

4. With regard to examples, during the negotiation of the SPS Agreement an oft-discussed example was damage to property arising from the entry, establishment or spread of termites.

121. With reference to Article 5.1 of the SPS Agreement, what were the relevant risk assessment techniques developed by the relevant international organizations that the European Communities had to take into account in the relevant period (October 1998 - August 2003)?

5. As indicated in Annex A(3) of the SPS Agreement, the Codex is a relevant international organization with respect to food safety, and the International Plant Protection Convention (IPPC) is a relevant international organization with respect to plant health. The following Codex and IPPC documents set out the relevant risk assessment techniques for the period in question:

Codex standards:

- (1) Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, Section III, Codex Procedural Manual, 14th edition.
- (2) CAC/GL 44 2003 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- (3) CAC/GL 45 2003 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants

IPPC Standards:

- (4) ISPM # 02: 1996: Guidelines for pest risk analysis
- (5) ISPM # 06: 1997: Guidelines for surveillance
- (6) ISPM # 11 Rev. 1 (2003): Pest Risk Analysis for quarantine pests including analysis of environmental risks.

122. Please explain your views as to the relationship between a Member's appropriate level of protection and the requirement in Article 5.1 to ensure a measure is based on a risk assessment, as appropriate to the circumstances. Is the appropriate level of protection relevant to the conduct of the risk assessment?

6. The SPS Agreement indicates that the "appropriate level of protection" and "risk assessment" are distinct concepts. Annex A defines a "risk assessment" as an "evaluation" of particular risks. Once conducted, the risk assessment – that is, the evaluation of certain risks – is then used to decide whether to impose a measure because otherwise the risk would be greater than the appropriate level of protection.

7. The distinction between the "appropriate level of protection" and "risk assessment" are reinforced by Articles 5.2 and 5.3 of the SPS Agreement. These articles specify at length the factors to be taken into account in conducting a risk assessment:

"5.2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment."

"5.3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks."

Notably, neither of these articles provides that the "appropriate level of protection" is one such factor to be taken into account in conducting a risk assessment. Rather, as indicated in Article 5.3, the "appropriate level of protection" is distinct from risk assessment, and that level is used to "determin[e] the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk.

123. Please assume for the sake of argument that Article 5.7 of the SPS Agreement provides for an exception in the nature of an affirmative defence:

- (a) Could the Panel assess the merits of any such defence without having previously found an inconsistency with Article 2.2 of the SPS Agreement?**
- (b) If not, in a case such as this one where a claim of inconsistency with Article 2.2 of the SPS Agreement is based on a claim of inconsistency with Article 5.1 of the SPS Agreement, would it be correct for the Panel to begin its analysis with the Article 5.1 claim, then move to the consequential Article 2.2 claim and finally turn to the Article 5.7 defence?**

8. *Subpart (a).* As a general matter, it is *possible* to examine the validity of an affirmative defense under the WTO Agreement without first finding a substantive violation of a WTO obligation. If the EC is willing to simply concede that its measure is not based on a risk assessment and would be inconsistent with Article 2.2 except for Article 5.7, then the Panel could find a breach of Articles 2.2 and 5.1 and proceed directly to an examination under Article 5.7. However, unless the EC so concedes, it would not be practical to address Article 5.7 without first addressing the inconsistency of the EC's measures with Articles 2.2 and 5.1 of the SPS Agreement. Furthermore, Articles 2.2, 5.1, and 5.7 are closely interrelated, so an analysis under Article 5.7 would necessarily involve an examination of many of the same underlying issues as an analysis under Articles 2.2 and 5.1. Specifically, since Article 5.7 only applies where there is insufficient evidence to conduct a risk assessment, and where the Member has sought to obtain additional information necessary for a risk assessment within a reasonable period of time, the Panel would in any event have to analyze the sufficiency of any purported risk assessment or steps to complete one (which would seem to require an analysis under Article 5.1) before being able to make a finding under Article 5.7. In addition, in prior disputes involving Article 5.7 of the SPS Agreement, panels and the Appellate Body have examined Articles 2.2 and 5.1 before turning to Article 5.7.¹

¹ See *Japan – Apples*, AB-2003-4, Part V, and *Japan-Agricultural Products*, AB-1998-8, Parts VII and VIII.

9. *Subpart (b)*. For the above reasons, the United States agrees that the most efficient way to organize an analysis of the EC measures *vis a vis* a possible Article 5.7 defense would be to begin the analysis with the Article 5.1 claim, then move to the consequential Article 2.2 claim and finally turn to the Article 5.7 defence.

For all complaining parties:

124. With reference to para. 19 of the European Communities supplementary rebuttal, do the complaining parties agree that the Panel "is not asked to determine whether a prudent government, in the abstract, should have behaved or not in a certain manner thus causing delay. It merely needs to find whether, in the concrete case and in light of the factual information and the legal arguments before the relevant authorities, that behaviour which in the end caused a delay could justifiably have been adopted"?

10. The United States does not agree with the EC's formulation of the pertinent question before the Panel with regard to findings related to the issue of "undue delay" under Annex C. In particular, the above-cited language from the EC supplementary rebuttal is addressed to the standard of review to be adopted by the Panel in examining whether certain delays were "undue," and the EC appears to be arguing that such standard must involve some sort of special deference or that the Panel needs to put itself into the position of the "relevant authorities" and second-guess the courses action available at a given point in time.

11. With respect to deference, in the *EC-Hormones* dispute, the Appellate Body addressed the standard of review to be used in examining measures under the SPS Agreement. In that case, like in the present case, the EC was arguing that a special standard of review had to be adopted for purposes of applying the SPS Agreement. The Appellate Body rejected the EC argument, and set out the following standard of review:

So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither *de novo* review as such, nor "total deference", but rather the "objective assessment of the facts". Many panels have in the past refused to undertake *de novo* review, wisely, since under current practice and systems, they are in any case poorly suited to engage in such a review. On the other hand, "total deference to the findings of the national authorities", it has been well said, "could not ensure an 'objective assessment' as foreseen by Article 11 of the DSU".²

12. The United States submits that in applying the disciplines of the SPS Agreement, the Panel should cite to and employ the above standard of review applied by the Appellate Body. The EC has not provided any basis for the Panel to adopt any different standard of review for the purposes of this case.

13. With respect to "second-guessing," the question is whether there was any "delay" and if so was it "undue." It is not a question of having to reconstruct what relevant authorities "could" have been thinking at any particular point in time.

² *EC – Hormones*, para. 117.

125. The European Communities' opening statement at the Panel's meeting with the experts includes the following statements:

"The European Communities' approach is to seek more evidence to establish whether or not there is a risk ... in order to make a definitive decision on the basis of full information - even if that takes a little more time". (para. 19)

"The European Communities reacts to uncertainty as to the appropriate risk management strategies by saying 'let's take our time and reduce the uncertainty". (para. 17)

Do the complaining parties consider that it would be consistent with Annex C(1)(a) of the SPS Agreement to delay making a definitive decision based on the approach outlined by the European Communities? In answering this question, please take into account the provisions of Article 2.2 of the SPS Agreement and Article 5.7 of the SPS Agreement (adoption of provisional measures based on available pertinent information).

14. The above statements by the EC are so vague and general that is not possible to analyze precisely how those statements might apply to the facts of this case or to the relevant disciplines set out in the SPS Agreement. However, the United States disagrees with the tenor of the EC comments on several levels.

15. First, the above statements by the EC imply that this dispute simply involves decisions by the EC to "take a little more time." But that characterization fundamentally misstates the key issue in this case : namely, that the EC adopted an *across-the-board moratorium* on all biotech products for a period of *five years*, and applied that moratorium regardless of the particular facts and circumstances of particular product applications.

16. Second, as the United States highlighted in its oral statement at the second panel meeting, the Panel must reject the EC's suggestion that all analyses under the SPS Agreement must be seen in the light of "uncertainty." In fact, the responding party in the *Apples* case similarly relied on a general theme of uncertainty, and the Appellate Body firmly rejected it:

The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to "cases where relevant scientific evidence is insufficient", not to "scientific uncertainty". The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of "scientific uncertainty".³

17. Third, to the extent the Panel decides to examine individual instances of delay in the histories of particular product applications, the issue is whether or not the delay is "undue," based on the facts and circumstances of that particular application, and taking account of the fundamental fact that the EC adopted and applied an across-the-board moratorium. The broad generalizations set out by the EC are neither accurate, nor helpful in the analysis of particular delays. What is much more relevant is that for many products, the lead competent authorities and relevant EC scientific committees determined that sufficient evidence was available, conducted risk assessments, and determined that the products are safe. The scientists on these committees did not consider additional evidence was necessary - indeed

³ Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003, para. 184.

they rejected the member States' claims of uncertainty. It was the EC regulatory bodies who declined to act on the scientific assessments that had already been conducted.

18. Fourth, the EC statements could be read as supporting a view that a WTO Member may delay consideration of applications indefinitely while the Member searches for purely theoretical risks. As the United States explained at the second substantive meeting, the SPS Agreement cannot be construed to allow Members to put impossible burdens on applicants to prove the negative – for example, to prove that there are no adverse impacts on any and all, unspecified, aspects of the environment. Such types of questions necessarily result in endless delay, which in turn must be considered "undue." Otherwise, a WTO Member could block all product approvals, indefinitely, by posing such vague and general questions.

19. Fifth, the United States considers that Article 5.7 could be relevant context to be examined in deciding how to apply the "undue delay" provision of Annex C. For example, delaying consideration of applications until the applicant responds to impossibly vague questions on theoretical risks would have an effect similar to the adoption of a ban on a product. Such a ban would not likely be consistent with Article 5.7 because it could not be based on "available pertinent information" where any risks raised by the Member were vague and purely hypothetical. In addition, in this example, there would be no way for the Member to seek to obtain the additional information necessary for a risk assessment within a reasonable period of time because the Member had not even identified the particular risks that needed further examination.

20. Finally, the very nature of science is that there will always be the potential for more evidence, there can never be an absolute certainty as to the lack of "a" risk, and information is never "full". Accordingly, the EC's approach would mean that a Member could always delay indefinitely any approval while awaiting "more" evidence and "full" information. The United States also cannot help but be struck by the contradiction between the EC's statements in paragraphs 17 and 19. On the one hand, in paragraph 17, the EC presumes there is a risk when it refers to "appropriate *risk* management strategies." On the other hand, the EC in paragraph 19 is still trying to determine if there *is* a risk.

126. In paragraph 10 of the EC Responses to the Questions from the Panel (16 June 2004), the European Communities compares the definitions of risk assessment as used in the SPS Agreement and as used in Codex, and concludes that "It is clear that the SPS definition of risk assessment is equivalent to 'weighing policy alternatives in the light of the results of risk assessment' which is part of the Codex Definition to "risk management". Do you agree with this conclusion? Please explain your response.

21. We disagree with the conclusion of the EC that the SPS definition of risk assessment encompasses risk management. The SPS Agreement provides that a risk assessment involves the "evaluation" of risks. SPS Agreement, Annex A(4). In doing so, Members may take into account "relevant inspection, sampling, and testing methods," (SPS Agreement, Article 5.2), but the *selection* of appropriate risk management measures goes beyond the *evaluation* or *assessment* of risks.⁴ Rather,

⁴ The EC's citation to the Appellate Body report in *EC-Hormones* does not support the EC's contention that risk assessment includes risk management. In *Hormones*, the Appellate Body was simply noting that in assessing risks, a Member may take account of the effectiveness of risk management measures related to those risks. Indeed, as noted above, the SPS Agreement specifically notes that risk assessment may take account of risk management measures such as inspection, sampling and testing methods. However, nothing in the *Hormones* Appellate Body report states or implies that the process of risk assessment includes decisionmaking on risk management measures. See *EC – Hormones*, AB-1997-4, paras. 181 and 206.

selecting appropriate risk management measures involves a policy determination and the weighing of policy considerations.

22. This is wholly consistent with the Codex definition of risk analysis, which distinguishes risk assessment from risk management. The Codex definition specifically notes that risk management is the process of weighing policy alternatives to address the risks defined by the risk assessment. In addition, we would note that the EC omitted a critical part of the Codex definition of risk management: "The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options." [emphasis added] Codex Procedural Manual, 14th Edition; Page 48.

127. At para. 42 of Canada's supplementary rebuttal, Canada suggests that crop husbandry includes breeding and that if a scientist employs selective breeding methods in the laboratory, this should qualify as crop husbandry because the scientist would be performing the same operations as a farmer who employs selective breeding methods on the farm. But is the insertion of a transgene part of the breeding of biotech crops? Or is the breeding rather the re-production of the biotech seed?

23. Breeding includes the insertion of a transgene as well as the reproduction of biotech seed. As defined by Webster's New World Dictionary of the American Language, breeding is "the producing of plants and animals, especially for the purpose of improving the stock." The introduction and selection of new genetic traits, irrespective of the method by which this is accomplished, is an essential component of plant breeding. Canada correctly asserts that modern methods of plant breeding, a subset of crop husbandry, range from techniques typically associated with traditional breeding to the utilization of modern genetics. Current methods to generate new and improved plant varieties include cross hybridization and natural selection in the field but also encompass variation introduced by modern laboratory techniques such as tissue culture, embryo rescue and genetic transformation.

Questions not Previously Provided to the Parties

For all parties:

140. With reference to (1) Codex standards 192 and 193, (2) IPPC and (3) ISPM 11:

- (a) Are they "rules of international law applicable in the relations between the parties to this dispute " within the meaning of Article 31(3) of the Vienna Convention on the Law of Treaties?**
- (b) May they be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement, as the United States appears to suggest in its rebuttal at para. 6 of attachment II? (The United States is invited to provide elaboration on its statement at para. 6.)**

24. *Subpart a:* Whether Codex and IPPC standards are "relevant rules of international law" for purposes of the Vienna Convention of the Law of Treaties presents a theoretical question that the Panel need not address in the context of this dispute. Instead, as noted in response to Question 121 above, Annex A of the SPS Agreement specifically refers to standards, guidelines, and recommendations adopted by the Codex and IPPC. Accordingly, there is no need to address the relevance of Codex and IPPC standards under more general rules of treaty interpretation.

25. As the United States noted previously, definitions in Codex and IPPC documents may be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement. Delegates to organizations such as Codex and IPPC are generally knowledgeable in their respective fields, and the fact that those organizations adopt particular definitions of terms should be considered pertinent to the ordinary meaning of those terms. Or, put another way, it would not make sense to consider *only* definitions drafted by the authors of general purpose dictionaries while *excluding* any consideration of definitions adopted by persons knowledgeable in their fields. However, the evaluation of the importance of any particular definition must be made on a case-by-case basis. For example, Codex or IPPC drafters may have special reasons to adopt a narrow definition of particular terms in order to limit the scope of a standard to issues of concern to their respective organizations. Such a narrowly drafted definition would not indicate that a term lacked a broader, more common definition.

141. With reference to Annex (B)(1) of the SPS Agreement, please answer the following questions:

- (a) **Does the term "sanitary and phytosanitary regulations" cover administrative decisions which relate to the operation of approval procedures and which are generally applicable?**
- (b) **May the phrase "sanitary and phytosanitary regulations which have been adopted" be interpreted to encompass also sanitary and phytosanitary regulations which have been adopted de facto (e.g., generally applicable decisions which have been reached informally and which are unrecorded)?**

26. *Subpart a:* Yes, the term "sanitary and phytosanitary regulations" covers administrative decisions which relate to the operation of approval procedures and which are generally applicable. This is made clear by footnote 5 to Annex B, which provides that "sanitary and phytosanitary regulations" are "sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally."

27. *Subpart b:* Yes, the phrase "sanitary and phytosanitary regulations which have been adopted" may be interpreted to encompass also sanitary and phytosanitary regulations which have been adopted de facto. *First*, nothing in the text of the agreement provides that such measures must be adopted in a written form. *Second*, to exclude unwritten, de facto measures would make meaningless the transparency obligations of Annex B. Annex B requires that SPS regulations of general applicability must be "published promptly." If unwritten measures were excluded from Annex B, a WTO Member could avoid its transparency obligations simply by adopting de facto, unwritten measures of general applicability.

142. Please explain the meaning and rationale of the requirement in Article 2.2 that SPS measures be "based on scientific principles" and how this is different from the requirement that SPS measures not be maintained "without sufficient scientific evidence".

28. In Article 2.2, the requirements that measures must be "based on scientific principles" and not be maintained "without sufficient scientific evidence" are distinct but related requirements. Based on "scientific principles" means that the rationale for the measure must be based on scientific principles, including, for example, the use of the scientific method (that is, posing a hypothesis and testing that hypothesis through experiment). A measure based, for example, on pure superstition would not be based on "scientific principles." In contrast, "sufficient scientific evidence" relates to actual evidence that the product covered by the measure poses a risk covered within the scope of the SPS Agreement.

143. The Panel notes a number of instances where the same or a related product was apparently submitted under separate applications for approval. This appears to be the case for Monsanto Roundup Ready oilseed rape GT73 (EC-70, EC-79); Syngenta Bt 11 maize (EC-80, EC-92, and related EC-69); Pioneer/Dow AgroSciences Bt corn Cry1F (1507) (EC-74, EC-75, EC-95); Monsanto Roundup Ready corn NK603 (EC-76, EC-96); Monsanto Roundup Ready corn GA 21 (EC-78, EC-85, EC-91); and the various "stacked" products. To what extent does the assessment by a lead CA, the relevant EC Scientific Committee and any information provided by a notifier under one application serve as a basis for consideration of another application for the same or a related product?

29. The data provided are fundamentally similar for submissions made under Dir 90/220 (2001/18) and Novel Foods Reg 258/97; however, the scope of the applications, and therefore the endpoints of the respective risk assessments, may be dissimilar.

30. Taking the Member States first, most have separate CA secretariats (often in different ministries) and separate expert committees for applications under the two statutes. An assessment under one statute would, therefore, probably not inform an assessment under the other. That said, certain applications under Dir 90/220 in the UK, for example, were also seen by the CAs and/or experts responsible for Reg 258/97. Similarly, certain national expert committees have accountability under both statutes, e.g. COGEM in the Netherlands. It is not possible, therefore, to give a generally applicable answer to this question, since national arrangements vary.

31. At the EC level, the two statutes were administered by separate DGs (ENV and SANCO, respectively) and assessed by separate scientific committees (the SCP and SCF, respectively) until the creation of the joint Novel Foods/GMO working group (early 2001) and, subsequently, the GMO panel of EFSA. Since 2001, an assessment under one statute would, therefore, inform an assessment under the other.

144. The Panel notes that a number of products containing the same transgenic modifications as products at issue in this dispute were previously approved by the European Communities prior to July 1998 (eg, swede rape tolerant to glufosinate ammonium (MS1, RF1) and (MS1, RF2); swede rape tolerant to glufosinate ammonium (Topas 19/2); maize tolerant to glufosinate ammonium (T25); maize expressing the Bt cry1A(b) gene (MON 810); maize tolerant to glufosinate ammonium and expressing the Bt cry1A(b) gene (Bt-11); soybean tolerant to glyphosate; chicory tolerant to glufosinate ammonium; maize Roundup Ready NK603). To what extent and how were the previous assessments of potential risks to human, animal or plant health and/or the environment associated with these transgenic modifications taken into consideration in the evaluation of potential risks arising from the products at issue before the Panel?

32. Government regulatory authorities with experience in regulating plants produced through modern biotechnology do so by evaluating data for individual products (case-by-case approach). It is normal practice for regulatory authorities to use this case-by-case approach within the context of existing, generally accepted scientific knowledge. Thus, safety data on an individual product is evaluated along with what is known, for example, of the biology of a particular plant species, how proteins generally function, and the history of use of the trait that has been introduced into the plant. In other words, regulators do not evaluate product-specific safety data in a scientific vacuum.

33. If the same Bt protein (e.g. the Bt protein produced by the Bt cry1A(b) gene) is produced in different types of plants, the safety parameters of the protein (e.g., mode of action, potential for toxicity

to humans and allergenicity) are not likely to differ in different types of plants. With respect to potential effects on non-target organisms, again, the mode of action of the protein—and therefore the potential for adverse effects-- would not be different in different plants but there could be different ranges of exposure across plant species. Similar considerations would be given if the same mechanism of herbicide tolerance is introduced into different types of plants.

34. Given the paucity of explanations presented by EC member States when presenting additional questions on applications, the extent to which EC regulators actually took account of data from related applications is uncertain. However, EC regulators did have the discretion to consider such data, and on occasion EC regulators explicitly did so. See, for example, EC 74 (Pioneer BT maize event 1507), attachment 36, question 11 from the lead CA to the applicant: "Results that demonstrate the equivalence (e.g. amino acid sequence, molecular weight) of PAT expressed in transgenic maize line 1507 to PAT expressed in crops previously approved under 90/220/EC should be supplied."

For all complaining parties:

145. With reference to para. 7 of the European Communities second oral statement, is it "for the Complainants to rebut this evidence [submitted by the European Communities] by putting forward arguments and evidence as to why reasons for delays put forward in the European Communities' submissions are unjustified"?

35. As the United States explained at length in its oral statement at the second substantive meeting, the complainants do not have the burden of proving or disproving that any particular delay was unjustified. Rather, the United States presented a clear and compelling case that the EC adopted an across-the-board general moratorium on biotech approvals. Under that moratorium, applications were allowed to make some progress, but no application was allowed to reach final decision. In other words, as long as certain member States opposed the approval of biotech products as a matter of principle, and as long as the Commission was unwilling to submit product applications to votes by member State and then to the Commission itself in the face of such opposition, no product could ever be approved under the moratorium. Thus, the United States does not have the burden of establishing that particular delays were justified or unjustified. Moreover, as previously explained, the fact that certain questions by EC regulators were warranted is to be expected, and is not at all inconsistent with an across-the-board moratorium on final decisions.

For the United States:

149. In your comments on the experts' replies to the Panel's Question 4, you have indicated that given the availability and use of insect resistance management (IRM) strategies, the delay of Bt crop applications under the EC's pre-market approval system "cannot be justified by alleged concerns over the emergence of Bt-resistance where objecting member States failed to address the validity to the IRM plans already submitted by applicants, particularly when those plans were deemed acceptable by the relevant EC scientific committees." Please identify those products (include the EC-chronology numbers) where you believe that an objecting member State failed to address the validity of plans already submitted, and particularly identify those products for which the relevant EC scientific committees had found the IRM plans acceptable.

36. IRM plans were submitted for the following products, both as part of the original notification, and again, as part of the updated notifications submitted pursuant to 2001/18:

- (1) Bt Cotton, Event 531, EC Exhibit 65.
- (2) Bt-11 Corn, EC Exhibit 69

(3) Bt Cry 1F Corn, Event 1507, EC Exhibit 75.

In the case of Bt cotton, 531, an amended plan was submitted in response to Member State concerns, but then no action appears to have been taken for a period of over four years. In the case of the two corn products, individual Member States objected, raising concerns with respect to the development of insect resistance, without addressing the validity of the IRM plans that had been submitted.

As noted above, the applicant submitted an IRM plan as part of its original notification.⁵ In 1998, in response to Member State concerns, the applicant adapted the plan to address the "particular cotton cultivation conditions in Spain and in Greece [and to] take into account the biology and susceptibility of the major European lepidopteran target-pests, the market structure, average farm size and market penetration in the cotton cultivation areas and the need to work closely with farmers and extension services to educate and implement the plan."⁶ According to the chronology, no action was taken on the application between 1999 and 2003, when the applicant updated its notification in accordance with Directive 2001/18.

Regarding Bt-11 corn (EC Exhibit 69), the applicant submitted an IRM plan as part of its original notification, submitted in 1996.⁷ In 1998, the French advisory Committee issued a positive opinion that explicitly considered the potential for development of insect resistance.⁸ Subsequently, both Italy and Denmark both raised objections relating to the possible development of insect resistance, and the need for further information, but wholly failed to address the applicant's IRM plan. Notwithstanding the applicant's IRM plan, Italy merely objected that "taking into account all the aspect concerning the use of a plant which expresses resistance to lepidopters, it is necessary to foresee a monitoring plan, aiming to obtain information concerning possible rising of resistance..."⁹ Similarly, Denmark simply objected on the grounds that "[t]he expert group on monitoring development of insect resistance should end their work before any consent is given to introduce Bt plants to the market. New information on possible development of resistance should be included in the work from the expert group."¹⁰

In 2000, after evaluating the notification, including the applicant's IRM plan, the SCP also issued a favorable opinion.¹¹ In section 4.5.4, the SCP discussed its findings relating to the potential development of insect resistance, stating

Although it is not possible to determine optimal dose until resistant insects exist in the field, high protein levels appear present in all important plant tissues early in the season and should provide season long control. The success of the resistance management strategy will depend on the ability of any monitoring program to detect resistance as soon as possible and the extent and quality of advice given to farmers. The SCP published an opinion on 4 March 1999 on resistance monitoring [citation omitted] as developed by the Expert Group on Monitoring for Insect Resistance to Bt-

⁵ EC Exhibit 65, att. 3-17, appendix 7.

⁶ EC Exhibit 65, att. 49.

⁷ EC Exhibit 69, att. 3, pp 159-168

⁸ EC Exhibit 69, att. 26, p 4.

⁹ EC Exhibit 69, att 60, p. 4.

¹⁰ EC Exhibit 69, att 66, p. 2.

¹¹ EC Exhibit 69, att. 83, p. 9.

toxins. Such monitoring should be carried out in Bt-maize and should provide an adequate framework to delay the onset of resistance in the target pest.¹²

In 2003, the applicant submitted an updated notification, pursuant to Directive 2001/18, that included an updated IRM plan.¹³ Shortly thereafter, the French advisory Committee issued a positive opinion on the notification. This opinion specifically addressed the potential for the product to cause insect resistance and concluded that the applicant's plan was acceptable.¹⁴ Nonetheless, Italy objected, citing concerns about the potential emergence of insect resistance, but entirely failing to address the particulars of the applicant's IRM plan.¹⁵ Spain also objected on the grounds that an IRM plan was necessary, failing in any respect to address the fact that the applicant had submitted an IRM plan.¹⁶

The case is similar with respect to Bt cry 1F Corn 1507, (EC Exhibit 75). As part of both the original application, and the updated notification submitted pursuant to Directive 2001/18, an IRM plan was submitted.¹⁷ Upon reviewing the IRM plan, the Spanish National Biosafety Committee concluded that "an adequate Resistance Management Plan will be applied," and recommended that the product be approved.¹⁸ Nonetheless, Austria objected, stating that "a complete remedial plan should be worked out before the placing on the market of this product."¹⁹ At no point does the objection identify a specific deficiency in the applicant's proposed IRM plan, or otherwise address the particulars of the proposal.

150. In paragraph 97 of the US Answers to Questions Posed in the Context of the First Panel Meeting (16 June 2004), you indicate that "Directive 90/220 does not precisely specify the time of each step, but appears to contemplate a time-frame from application to decision of no more than 1 year". What is the basis for this statement?

37. The conclusion that Directive 90/220 appears to contemplate a time-frame from application to decision of no more than 1 year is based on the following analysis of the time frames in the directive. The directive provides roughly eight months for all timelines specified for the key steps in the approval process: favourable member State opinion within 90 days (Art.12 para 2), plus member State review of 60 days (Art.13 para 2), plus Article 21 procedure of 3 months (Art. 21, para 5). The remaining steps in the legislation are procedural, with no decision element, such as forwarding dossiers from the member State level to the Community level. It would not be sensible for those procedural steps to be expected to take longer than the time for the substantive processes, which total eight months. Even if those procedural steps took one half as long, or four months, the total processing time would be no more than one year.

151. With reference to paragraph 12 and 14 of the US statement on 22 February 2005, for the convenience of the Panel please identify all documents (according to the EC exhibit/attachment number) which you consider contain specific statements acknowledging or attesting to the existence of a de facto moratorium.

¹² EC Exhibit 69, att.83, p. 9.

¹³ EC Exhibit 69, att. 104, pp 93-110.

¹⁴ EC Exhibit 69, att. 95, p 5.

¹⁵ EC Exhibit 69, att. 112, p 6.

¹⁶ EC Exhibit 69, att. 122

¹⁷ EC Exhibit 75, att.1; att.22 & 23, pp. 23-55..

¹⁸ EC Exhibit 75, att.29, p. 7.

¹⁹ EC Exhibit 75, att. 85, p.3.

38. In the attached Table 1, the United States has provided examples of the many instances in which the EC's own product application histories acknowledge a de facto moratorium. This evidence, of course, is in addition to the many acknowledgments of the moratorium contained in the exhibits presented by the United States in its first submission and first oral statement.

For the European Communities and the United States:

165. (EC-73): It appears that all of the relevant documentation was not provided in the context of the application contained in EC-73. However, the chronology provided by the European Communities shows no action on this application between the 02/00 requests for further information from the CA, and the 1/03 relaunch of the application under Directive 2001/18. Did the notifier fail to provide the information requested in 02/00, and if so, why?

39. The United States understands that the notifier did not provide the requested additional information.

166. (EC-74): As was noted in the replies by the experts, the complete documentation related to this dossier was not provided to the Panel. In some instances, the attachment provided only the titles of annexes, but not their contents. Please clarify whether the missing documentation had been provided to the lead CA, and if so, when?

40. In her response to Panel's question 34, Dr. Nutti said she was unable to find the quail feeding study within the files. Upon extensive review of the EC's CDs, the United States has located this study in EC-74, attachment 44.

41. Dr. Nutti further noted that EC-74, attachment 36 did not include all the referenced annexes. The Panel above similarly observes that in some attachments, only the titles of annexes have been provided, but not their contents. The attachments to which Dr. Nutti and the Panel are referring are the applicant's cover letters providing further information in response to the lead CA's requests for information. The United States has reviewed the documents provided to the Panel relating to EC-74 and has located all relevant annexes referenced in all of these cover letters. Most annexes referred to in these cover letters have been provided as separate attachments and are not included in the attachment containing the cover letter.

42. Thus, for example, attachment 35 is the applicant's October 16, 2001 cover letter listing further information being provided, including a narrative and annexes, but attachment 35 does not actually include the new information. Attachment 36 is the narrative answers to the lead CA's questions. The narrative lists the titles of annexes 1.B through 9.B, but attachment 36 does not include the annexes themselves. Instead, attachments 37, 40, 41, 42, 43, 44, 45, 47, and 48 are the actual annexes 1.B through 9.B.

43. Another less straightforward example is attachment 18, the applicant's February 14, 2001 cover letter listing further information being provided in response to the lead CA's December 15, 2000 request. The cover letter lists Annexes 1.A through 4.A, but the annexes are not included in attachment 18. Instead, attachment 28 is Annex 1.A. Annex 2.A is found in attachments 20 through 26. Attachment 29 is Annex 3.A. Attachments 30 and 31 are Annex 4.A. Attachment 19 is the narrative answers to specific questions. In addition, attachment 32 appears to be a duplicate of the entire submission, including the cover letter, the narrative answers, and all the annexes.

44. Similarly, the applicant's January 30, 2002 cover letter lists Annexes 1C through 5C. Although the cover letter is included in attachment 53, the annexes are not. These annexes are in attachments 55

through 59, respectively (the last few pages of attachment 59 appear to be the relevant pages for Annex 5C).

45. The United States also refers the Panel to EC-74, attachment 2, a document titled "Summary of the evaluation carried out by the Netherlands Competent Authority." This document notes that two different agencies, the COGEM, the Committee on Genetic Modification, and the RIKILT-DLO, the State Institute for Quality Control of Agricultural Products (among others), evaluated the dossier. The document notes that the COGEM requested additional information from the applicant on December 15, 2000, March 19, 2001, and March 25, 2002 and provided an opinion on January 15, 2003 that no significant potentially negative effects were identified related to the proposed placing on the market of the product. The document also noted that "[b]ased on an evaluation of the complete dossier, the RIKILT-DLO concluded that there is no indication that the product would not be safe when used as animal feed", its last opinion having been expressed April 16, 2003. Given these two agencies' positive safety assessments, the United States presumes that all relevant documentation had been provided to the lead CA.

46. Finally, in the experts' replies, specifically Dr. Nutti's replies to questions 33 and 34, Dr. Nutti stated that she was unable to recover the information on tables 10A, 11A, 12A and 13A in EC-74, attachment 19. The United States notes that it has been able to access the information from the copies of the CDs that the EC provided to the United States.

167. (EC-93): It appears that some of the documentation relevant to the safety assessment was not provided to the Panel. Please clarify whether the missing documentation had been provided to the lead CA, and if so, when?

47. The United States understands as follows. The applicant did provide the information requested, as indicated in the applicant's letter dated 18/07/01. The applicant received a response from the EC on 31 August 2001. The United States does not know why the information the applicant provided was not included in the product history CDs.

48. In the 31 August 2001 letter, additional information was requested regarding data about the composition of fibre constituents. The applicant responded to the 31 August 2001 letter, explaining why the information requested had already been provided or could be addressed with information that BCS had already provided.

49. The 31 August 2001 letter also requested or mentioned additional information (growth performance study and molecular characterisation) relating to event A5547 -127. The original file submitted contained two events - A2704-12 and A5547-127. The applicant made the decision to pursue only A2704-12 at that time and therefore elected not to provide requested information with respect to A5547-127.

For Canada, European Communities and the United States:

168. (EC-72): The Panel notes that the chronology provided by the European Communities shows no actions on this application between 12/99 (when according to the European Communities the UK CA allegedly advised the company that the dossier required substantial revision and clarification) and its re-submission in 1/03 under Directive 2001/18. Could the parties please explain the lack of action?

50. The United States understands that the applicant did not provide the data requested in December 1999.

For Argentina, European Communities and the United States:

169. With respect to the safeguard measures invoked for Maize Bt-176, please list the scientific evidence on which the concerns raised by Austria and Germany on potential adverse effects on non-target organisms were based (August 2003).

51. A. The scientific studies that were explicitly cited by Austria and Germany in connection with the safeguard measures applicable to Maize Bt-176, and that address issues relating to effects on non-target organisms have been listed below.

Studies cited by Austria

EC (European Commission): The European Commission has decided to authorize genetically modified maize in the light of available scientific advice. Press release including summary conclusions of the three scientific committees. 18.12.1996.²⁰

EPA (1995a) Pesticide Fact Sheet. Cry IA(b). *Bacillus thuringiensis* cry IA (b) Delta-Endotoxin and the Genetic Material Necessary for its Production (Plasmid Vector pCIB4431) in Corn. US EPA, Office of Prevention, Pesticides, and Toxic Substances, 10.8.1995²¹

EPA (1995b) Pesticide Fact Sheet. Cry IA(b). *Bacillus thuringiensis* subsp. *Kurstaki* cry IA (c) Delta-Endotoxin and its Controlling Sequences as Expressed in Cotton. US EPA, Office of Prevention, Pesticides, and Toxic Substances, 10.8.1995.²²

EPA (1996) Pesticide Fact Sheet. *Bacillus thuringiensis* Delta-Endotoxin and the Genetic Material Necessary for its Production (Plasmid Vector p201502) in Corn. US EPA, Office of Prevention, Pesticides, and Toxic Substances, 5.8.1996.²³

Gould, F. (1994): Potential and Problems with High-Dose Strategies for Pesticidal Engineered Crops. In: *Biocontrol Sci. Tech.* 4(4), 451-461.²⁴

Hokkanen; H. And Deacon, J (eds.) (1994): Special Issue: OECD Workshop on Ecological Implications of Transgenic Crop Plants Containing *Bacillus thuringiensis* Toxin Genes. In: *Biocontrol. Science and Technology* Vol.4.²⁵

Höfte, H. and Whiteley, H.R. (1989): Insecticidal crystal proteins of *Bacillus thuringiensis*. *Microbiol. Rev.* 53, 242-255.²⁶

Kaiser (1996): Pests Overwhelm Bt Cotton Crop. *Science* 273, 423.²⁷

²⁰ EC Exhibit C/F/94/11-03, att 1

²¹ Id.

²² Id.

²³ Id.

²⁴ Id.

²⁵ Id.

²⁶ Id.

²⁷ Id.

- Macilwain (1996): Bollworms chew hole in gene-engineered cotton. *Nature*. 382, 289.²⁸
- Milner, R. (ed) (1994): Special Issue: *Bacillus Thuringiensis*. *Agric., Ecosys. Env.* Vol. 49.²⁹
- Ogunseitan OA (1995) Bacterial genetic exchange in nature. *Sci Prog.* 78: 183-204.³⁰
- Ow.D.W. (1996): Recombinase-directed chromosome engineering in plants. *Curr. Op. Biotech* 7, 181-186.³¹
- Ow.D.W. and Medberry, S.L. (1995): Genome manipulation through site-specific recombination. *Crit. Rev. Plant Sci.* 14, 239-261.³²
- Roush, R.T. (1994): Managing Pests and their Resistance to *Bacillus thuringiensis*: Can Transgenic Crops be better than Sprays? In: *Biocontrol Sci. Tech.* 4(4), 501-516.³³
- Sharma UK. (1993), Insights into plasmid biology. *Curr. Sci.* 64: 283-285.³⁴
- Salyers AA et al (1995) Conjugative transposons: an unusual and diverse set of integrated gene transfer elements. *Microbiol. Rev.* 579-590.³⁵
- Tapp, H. And Stotzky, G. (1995): Insecticidal Activity of the Toxins from *Bacillus thuringiensis* subspecies *kurstaki* and *tenebrionis* Adsorbed and Bound on Pure and Soil Clays. *Appl. Env. Microbiol.* 61(5), 1786-1790.³⁶
- Whalon, M.E. and Norris, D.L. (1996) Resistance Management for Transgenic *Bacillus thuringiensis* plants. *Biotechnology and Development Monitor* 29, 8-12.³⁷
- Gould, et al.; PNAS - <http://www.pnas.org/cgi/content/full/94/8/3519#abs>³⁸
- Tabashnik, et. al.; PNAS - <http://www.pnas.org/cgi/content/full/94/5/1640>³⁹
- "Biodiversity Implications of Genetically Modified Plants", International Scientific Conference, Ascona/Switzerland, September 2003.⁴⁰
- Ruud de Maagd, "Molecular and biochemical analysis of the Bt-corn/cotton leafworm/green lacewing trophic interaction"; oral presentation at "Biodiversity Implications of Genetically Modified Plants", International Scientific Conference, Ascona/Switzerland, September 2003.⁴¹

²⁸ Id.

²⁹ Id.

³⁰ Id.

³¹ Id.

³² Id.

³³ Id.

³⁴ Id.

³⁵ Id.

³⁶ Id.

³⁷ Id.

³⁸ EC Exhibit C/F/94/11-03, att 5.

³⁹ EC Exhibit C/F/94/11-03, att 6.

⁴⁰ EC Exhibit C/F/94/11-03, att 23.

⁴¹ Id.

Claudia Zwahlen, "Implications of transgenic *Bacillus thuringiensis* maize varieties in soil ecosystems"; oral presentation at "Biodiversity Implications of Genetically Modified Plants", International Scientific Conference, Ascona/Switzerland, September 2003.⁴²

Zwahlen, C., Hillbeck, A., Gugerli, P. & Nentwig, W. (2003a): Degredation of the Cry 1Ab protein within transgenic *Bacillus thuringiensis* corn tissue in the field. *Molecular Ecology*, 12, 765-775.⁴³

Zwahlen, C., Hillbeck, A., Gugerli, P. & Nentwig, W. (2003b): Effects of transgenic Bt corn litter on earthworm *Lumbricus terrestris*. *Molecular Ecology*, 12, 1077-1086.⁴⁴

Darvas, B., Kincses J., Vajdics Gy., Polgàr A., L., Juracsek J., Ernst, A., and Székács A. (2003): 49th Abs. Plant Protection Days, page 45.⁴⁵

Eva Vojtech, "Effects of Bt maize on the herbivore *Spodoptera littoralis* and the parasitoid *Cotesia marginiventris*", oral presentation at "Biodiversity Implications of Genetically Modified Plants", International Scientific Conference, Ascona/Switzerland, September 2003.⁴⁶

Darvas, B., Gharib, A., Csóti A., Székács A., Vajdics Gy., Peregovits, L., Ronkay, L. and Polgàr A., L. (2002): 48th Abs. Plant Protection Days, page 31.⁴⁷

Environmental Science and Technology, July 2003, p.249A (zeitert: *Proc. Natl. Acad. Sci. U.S.A.* 2003, 100, 5004-5009)⁴⁸

A.N.E. Birch, et al., SCIR/Dundee/Scotland, "Expecting the Unexpected"; oral presentation at "Biodiversity Implications of Genetically Modified Plants", International Scientific Conference, Ascona/Switzerland, September 2003.⁴⁹

Zwahlen, et al (2003), Degradation of the Cry1Ab protein within transgenic *Bacillus thuringiensis* corn tissue in the field. *Molecular Ecology*, 12, 765-775.⁵⁰

Zwahlen, et al (2003), Effects of transgenic Bt corn litter on the earthworm *Lumbricus terrestris*. *Molecular Ecology*, 12, 1077-1086.⁵¹

Morin, et al, PNAS – <http://www.pnas.org/cgi/doi/10.1073/pnas.0831036100>⁵²

Saxena, et al (2002), Bt toxin is released in root exudates from 12 transgenic corn hybrids representing three transformation events. *Soil Biology & Biochemistry*, 34, 133-137.⁵³

⁴² EC Exhibit C/F/94/11-03, att 23.

⁴³ Id.

⁴⁴ Id.

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ Id.

⁴⁹ EC Exhibit C/F/94/11-03, att 23.

⁵⁰ EC Exhibit C/F/94/11-03, att 25.

⁵¹ EC Exhibit C/F/94/11-03, att 26.

⁵² EC Exhibit C/F/94/11-03, att 27

⁵³ EC Exhibit C/F/94/11-03, att 28

Darvas & Szkacs, December 2, 2003: Bt-toxin levels in DK-440-BTY (YieldGard) Bt-corn and stubble. Effects of DK-440-BTY (YieldGard) Bt-corn pollen on *Inachis io* (Nymphalidae) larvae. Non-target effects of DK-440-BTY (YieldGard) Bt-corn.⁵⁴

Hilbeck, et al, Biodiversity Implications of Genetically Modified Plants: Abstract Book. September 7-12, 2003.⁵⁵

Nick Birch, et al, "Expecting the Unexpected: Potential Ecological Impacts of Unintended Metabolic Changes in GM and Conventional Crops" (PowerPoint presentation).⁵⁶

Studies/Information cited by Germany:

Losey, et al., 1999, Nature 399:214.⁵⁷

Hilbeck, et al., (1999) Prey-mediated effects of Cry1Ab Toxin and protoxin and Cry2A protoxin on the predator *Chrysoperla carnea*. *Entomologia Experimentalis et Applicata*, 91(2): 305-310.⁵⁸

Hilbeck, et al., (1998) Toxicity of *Bacillus thuringiensis* Cry1Ab Toxin to the Predator *Chrysoperla carnea* (Neuroptera: Chrysopidae). *Environmental Entomology*⁵⁹.

Hilbeck, et al., (1998) Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae). *Environmental Entomology*.⁶⁰

Saxena, et al., 1999, Nature 402:480.⁶¹

⁵⁴ EC Exhibit C/F/94/11-03, att 29.

⁵⁵ EC Exhibit C/F/94/11-03, att 30

⁵⁶ EC Exhibit C/F/94/11-03, att 31

⁵⁷ EC Exhibit C/F/94/11-03, att 16.

⁵⁸ EC Exhibit C/F/94/11-03, att 17

⁵⁹ EC Exhibit C/F/94/11-03, att 18

⁶⁰ EC Exhibit C/F/94/11-03, att 19

⁶¹ EC Exhibit C/F/94/11-03, att 20.

TABLE 1 – REFERENCES TO MORATORIUM IN EC APPLICATION HISTORIES

EC Exhibit	Product	Attachment #	Excerpt
62	InVigor Seed Link and Liberty Link	84	The Commission regards this as an opportunity to reinforce the provisions contained in its draft Decisions in a number of respects. It would therefore seem appropriate to suspend the current procedure and convene a meeting of the Committee as soon as possible.
		117_trans	[T]he existing situation could result in products being released on the market without being labelled for GMO, despite the fact that these products may within a rapid timeframe require such labelling. This it not satisfactory.
63	Oil seed rape	99	In May 1998, the Scientific Committee on Plants (SCP) of the European Commission expressed a positive opinion on the notification C/BE/96/01. They concluded that there is no evidence to indicate that the placing on the market of GM oilseed rape MS8/RF3, with the purpose to be used as any other oilseed rape, is likely to cause adverse effects on human health and the environment. ... Since then, the dossier has been blocked at European level by the de facto moratorium.
		102_trans	The Scientific Committee on Plants had also issued a positive opinion, but had raised questions concerning monitoring and agricultural practices. On 28 May 1999, the Commission had published a decision that had to be voted on. Given the <i>de facto</i> moratorium that had been in place since 1999, the dossier was bogged down in European procedures.
		102_trans	Mrs Janssens expressed the concern felt by the Office of Minister Aelvoet that the forwarding of this information could be interpreted as meaning that Belgium was pursuing the <i>ad interim</i> approach suggested by the European Commission, whereas in a recent consultation Belgium had clearly defended the standpoint that it did not agree with that approach and did not wish to continue processing dossiers on the marketing of GMOs until the new Directive, 2001/18/EU, had come into effect. The forwarding of the additional information relating to the Aventis CropScience dossier could come across as a signal to the opposite effect.
		102_trans	In order to go some way towards meeting the concerns of the Office of Minister Aelvoet, it was decided to attach an accompanying letter to the additional information, making it clear that the information was being forwarded to the Commission as required under Directive 90/220/EEC, but that this was not to be construed as a political signal to the effect that Belgium was in agreement with the application of an <i>ad hoc</i> approach and the lifting of the moratorium on the marketing of GMOs.
		102_trans	"... until such time as clarity is obtained regarding the moratorium and traceability, we are against field trials. The reason is that, while discussions are ongoing at European level, it is difficult to give a signal to a company to the effect that its proposal (revised to take future legislation into account) is a good one. This would be improper government practice, as it would send out the wrong signals to both the company and the population. Firstly, this would give the company the impression that the current European proposals would not undergo any further change. And secondly, it would give the population the impression that only the financial interests of a company were considered to be important." (signed: Jean-Pierre De Leener, advisor to the Flemish Minister of Agriculture and the Environment.
		102_trans	[T]he moratorium concerned only the marketing of GMOs and not their release for experimental purposes.
		106_trans	The draft recommendation was approved by the members of the Biosafety Council. [The Council emphasised] the importance of including a covering letter explaining that sending this update to the European Commission was not to be interpreted as a signal from Belgium that it wanted the current moratorium to be lifted.

EC Exhibit	Product	Attachment #	Excerpt
64		120	Having the revised directive fully adopted will not be sufficient. The re-start of the regulatory process will depend on the willingness of the Commission to do it. It is commonly analysed that the Commission will not promote an Art 21 vote meeting, if there are no indications that the member-states are supporting the process and/or expected to vote positively. Another key step for the member-states acceptance is the publication of Commission papers on traceability/labelling and liability that is expected by March 2001 (or later). These papers are very important because one of the reasons for the 5 member-states to start a moratorium was precisely labelling and traceability.
65		65	Members of the CNB are reminded that these two notifications of genetically modified cottons were studied in Spain within the framework of Directive 90/220/EEC. Spain drafted a favourable report, which was submitted to the European Commission, to which must be added the positive report by the Scientific Committee on Plants. However, both dossiers were put to the vote in 1999 and a qualified majority was not reached, so they remained pending and blocked during the <i>de facto</i> moratorium.
		65	Information was updated regarding the complaint against the EU submitted to the World Trade Organization (WTO) by the United States, Canada and Argentina, and nine countries supporting them, objecting to the moratorium it has maintained since 1998 on the approval of new genetically modified products.
66		65	Members of the CNB are reminded that these two notifications of genetically modified cottons were studied in Spain within the framework of Directive 90/220/EEC. Spain drafted a favourable report, which was submitted to the European Commission, to which must be added the positive report by the Scientific Committee on Plants. However, both dossiers were put to the vote in 1999 and a qualified majority was not reached, so they remained pending and blocked during the <i>de facto</i> moratorium.
		65	Information was updated regarding the complaint submitted to the World Trade Organization (WTO) by the United States, Canada and Argentina, and nine countries supporting them, against the EU objecting to the moratorium it has maintained since 1998 on approval of new genetically modified products.
67		91	The company was aware of the declarations of certain Member States in the June Council and wondered what effect this would have on the authorisation process
69		121	The lead competent authority issued "a favourable opinion on the placing on the market of the product [...] under the following conditions: [...] (iii) Placing on the market cannot be authorised until the Community regulations on the traceability and labelling of GMOs and on GM food and feed have entered into force." In accordance with the French position, the German CA is of the opinion that no consent should be given until both regulations are in force.
		125	Denmark also wants to draw attention to the declaration from March 2001 in which 6 Member States "reaffirmed their intention, when exercising the powers conferred upon them, of ensuring that the new authorisations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable labelling of all GMO products."
		149	Traceability and labelling: Consents for marketing GMOs should not be granted until all the requirements of the Regulation concerning traceability and labelling are applicable.
		158	Denmark finds that approval for placing on the market cannot take place before the regulation on traceability and labelling is fully into force.
		160	The Norwegian CAs are of the opinion that consents for marketing of genetically modified plants should not be granted until all the requirements of the Regulation concerning traceability and labelling (1839/2003) have been met and the Regulation is fully applicable.

EC Exhibit	Product	Attachment #	Excerpt
70		70	In addition, Denmark wants to draw attention to the declaration from March 2001 in which 6 Member States "reaffirmed their intention, when exercising the powers conferred upon them, of ensuring that the new authorisations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable labelling of all GMO products."
		72	The Swedish Society for Nature Conservation objects to the application for the following reasons: 1) products from animals that have eaten genetically modified feed shall be labelled, 2) the rules on traceability and labelling have not yet been implemented in national legislation, 3) the issue of liability for genetically modified organisms has not been solved at EU level, and 4) the decision should await the result from the study on coexistence. They therefore believe that the moratorium on genetically modified organisms should remain in place.
		76	[T]he French authorities point out that they are committed to the establishment of a European traceability and labelling system for GMOs and GMO-derived products and that consequently, the entry into force of the texts currently under adoption remains a prerequisite for authorizing the marketing of any new GMO.
		77	As a matter of principle, this product should not be placed on the market before the entry into force of the Regulation of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. In addition, further issues concerning liability and the coexistence of genetically modified, conventional and organic crops remain to be resolved.
		79_trans	[I]t seems reasonable not to base decisions authorizing the launch of the genetically modified foods on the currently applicable, yet generally considered inadequate, legislation but to wait for the new regulations to come into force. According to the Federal Government, the effective moratorium for approval of genetically modified organisms shall be terminated as soon as the regulations for permission and retrospective traceability of the genetically modified foodstuffs and fodders take effect.
		80	The official Belgian position as expressed during agriculture and environment councils is that as far as the regulation "Traceability and labelling of GMO and traceability of food and feed products produced from GMO" is not entered into force, the conditions for risk management and public information are not fulfilled to authorize new GMOs under Directive 2001/18. Moreover, it was also stated that the regulation "GM Food and Feed" should also enter into force prior to proceed to any new authorization.
		100	Even though this product is only destined for import and further processing in the EU, Austria - apart from the need for further information - maintains its objection against the putting of this product to the market, as long as all conditions for coexistence with GMO-free production methods and the issues concerning liability are not cleared in a sound legal way.
73		4	The field trials in Greece did not take place after the declaration of a moratorium on the cultivation of genetically modified crops.
		12	Members of the CNB are reminded that these two notifications of genetically modified cottons were studied in Spain within the framework of Directive 90/220/EEC. Spain drafted a favourable report, which was submitted to the European Commission, to which must be added the positive report by the Scientific Committee on Plants. However, both dossiers were put to the vote in 1999 and a qualified majority was not reached, so they remained pending and blocked during the <i>de facto</i> moratorium.
		12	Information was updated regarding the complaint against the EU submitted to the World Trade Organization (WTO) by the United States, Canada and Argentina, and nine countries supporting them, objecting to the moratorium it has maintained since 1998 on the approval of new genetically modified products.

EC Exhibit	Product	Attachment #	Excerpt
74		101	As long as the conditions for co-existence are not clarified on the EU level, Austria holds the opinion that no consent for the placing on the market of 1507 maize should be given, even though this notification is concerning import only.
		102	The German CA is of the opinion that no consent can be given until the Community regulations on the traceability and labelling of GMOS and on GM food and on feed have entered into force. In particular, the regulation on traceability and labelling of GMOs will provide for additional transparency and the possibility of choice for consumers.
		133	Furthermore, Denmark finds that approval for placing on the market cannot take place before the regulation on traceability and labelling is fully into force.
75		83	[T]he French authorities point out that the entry into force of the regulations on the traceability and labelling of GMOs and of food and feed products produced from GMOs, and on genetically modified food and feed, is a prerequisite for authorizing the marketing of any new GMO.
		85	As long as the conditions for co-existence are not clarified on the EU level, Austria holds the opinion that no consent for the placing on the market of 1507 maize should be given.
		86	Denmark also wants to draw attention to the declaration from March 2001 in which 6 Member States "reaffirmed their intention, when exercising the powers conferred upon them, of ensuring that the new authorisations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable labelling of all GMO products."
		87	The German CA is of the opinion that no consent can be given until the Community regulations on the traceability and labelling of GMOS and on GM food and on GM feed have entered into force. In particular, the regulation on traceability and labelling of GMOs will provide for additional transparency and the possibility of choice for consumers.
		88	Norway is of the opinion that the operational parts of the new EU regulations on traceability and labelling, as well as on genetically food and feed has to enter into force, and the management consequences of these regulations should be in place before any GMOs can be placed on the marked.
76		44	Irrespective of the above mentioned scientific objections raised, Austria is of the opinion, that products shall not be placed on the market before the new regulations concerning genetically modified food and feed as well as traceability and labelling of GMOs will enter into force. In addition the issue of co-existence of genetically modified, conventional and organic farming is at the moment under discussion and has to be resolved.
		44_trans	Notwithstanding the abovementioned scientific reservations, it must be stated generally that, before the new and planned provisions concerning the traceability and labelling of GMO, and concerning the authorization and labelling of GMO foodstuffs and feedstuffs, have come into force, Austria is in any case opposed to new authorizations.
		46	In addition, Denmark wants to draw attention to the declaration from March 2001 in which 6 Member States "reaffirmed their intention, when exercising the powers conferred upon them, of ensuring that the new authorisations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable labelling of all GMO products."
		47	The Swedish Society for Nature Conservation objects to the application for the following reasons: 1) products from animals that have eaten genetically modified feed shall be labelled, 2) the rules on traceability and labelling have not yet been implemented in national legislation, 3) the issue of liability for genetically modified organisms has not been solved at EU level, and 4) the decision should await the result from the study on coexistence. They therefore believe that the moratorium on genetically modified organisms should remain in place.

EC Exhibit	Product	Attachment #	Excerpt
		51	The official Belgian position as expressed during agriculture and environment councils is that as far as the regulation "Traceability and labelling of GMO and traceability of food and feed products produced from GMO" is not entered into force, the conditions for risk management and public information are not fulfilled to authorize new GMOs under Directive 2001/18. Moreover, it was also stated that the regulation "GM Food and Feed" should also enter into force prior to proceed to any new authorization.
		52	[T]he French authorities point out that they are committed to the establishment of a European traceability and labelling system for GMOs and GMO-derived products and that consequently, the entry into force of the texts currently under adoption remains a prerequisite for authorizing the marketing of any new GMO.
		54 (p. 28)	In general, we believe that it is unsuitable to proceed with the GMO authorisation process in absence of the final normative on labelling and traceability, export of GMOs (comprising the structure of the communication of information within the EU) as well as the new Food and Feed regulation
77		93 (p. 2)	Our conclusion now is that the dossiers for the evaluation of green hearted chicory and radicchio rosso for market authorisation under Regulation 258/97 are a kind of a "never ending story". The procedure, time, energy and costs are disproportionate compared to conventional breeding programs. This may lead to the conclusion that development and marketing of transgenic vegetable crops in the European Union do not have any opportunity.
78 + 85	Maize GA21	35	Lack of a coherent Community-wide traceability system. The French authorities note that no regulatory system ensures traceability until the end-user has been put in place.
		42	[T]aking into account the declarations given by the 12 ministers at the Council meeting in June 1999 ...
		61	Furthermore, without prejudice to this additional information, the establishment of a European traceability system for GMOs and GMO-derived products is, for the French authorities, a prerequisite for authorizing the marketing of new GMOs.
		71	[T]aking into account the declarations given by the 12 ministers at the Council meeting in June 1999...
91	Maize GA21		
92	Maize Bt11	23	The French authorities recall their position that, before any authorization, there must be legal and technical means whereby the traceability and labelling of GMOs and GMO-derived products can be ensured.
		27	Apart from this, however, Denmark will refer to the Declaration concerning the suspension of new GMO authorisations by five Member States (France, Greece, Italy, Luxembourg, and Denmark) at the Environment Council of 24 and 25 June 1999. With reference to this Declaration Denmark therefore wishes to submit a reasoned objection concerning the Bt11 maize.
		74	In view of the entry into force of the food/feed regulation on 18 April 2004 imposing more stringent requirements for marketing and labelling and the traceability regulation, on our view it is not at present appropriate to hasten marketing for food under a regulation which will be out of date in four months.
		75	Regulations 1829/2003 and 1830/2003 have not been implemented and as a result the novel product does not fully comply with the requirements ... We think there could be problems implementing the traceability systems.
		76	Portugal voted against the authorisation to place Bt11 on the market, since, under Community food safety policy, only the application of the traceability and labelling rules can guarantee the protection of public health and free choice for consumers.

EC Exhibit	Product	Attachment #	Excerpt
		80	In August 2000, Denmark submitted an objection to the approval of Bt11 maize in respect of the novel food regulation with reference to the declaration approved by Denmark, France, Italy, Greece and Luxembourg on the suspension of new GMO licences (the moratorium declaration), which was made at the Council meeting (environment) on 24-25 June 1999. The objection included a reference to the fact that, pending the approval of a regulation that would guarantee the labelling and effective tracing of GMOs and products derived from them, the moratorium countries would block any new licences for the cultivation and marketing of GMOs.
		80_trans	The proposal was put on the voting agenda for the meeting of the Standing Committee on the Food Chain and Animal Health on 8 December 2003, but a qualified majority in favour of the proposal was not achieved. Denmark voted against it on the grounds that it is evident from the regulation concerning traceability and labelling (1830/2003) that rules are to be drawn up for a system for the development and allocation of unique identifiers and technical guidelines for the sampling and analysis of GMOs. At the time of voting these rules had not been put into effect.
		84_trans	At the session on 20.4.2004 of the Standing Committee on Foodstuffs, Austria requested that no new products be admitted until the interpretation of the provisions on designation and traceability are sufficiently clarified.
95	CRY1F	25	Moreover, the rules on traceability and labelling laid down in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 must apply.
96	NK603	22_trans	Regardless of the scientific reservations expressed above, Austria is fundamentally opposed to the granting of any new approvals before the planned legislation on the traceability and labelling of GMOs and on the approval and labelling of GM food and feed is adopted and comes into force.
		23_trans	With regard to live GMOs, it should also be borne in mind that such products must be approved in accordance with the Directive on the release of GMOs and that the application must be considered to be covered by the moratorium. Denmark thus objects to the approval of this product ...
		24_trans	Given that the two regulations can be expected to enter into force fairly soon, it would seem appropriate to no longer take any decisions approving the introduction of genetically modified foods onto the market ...
		24_trans	In the German Government's view, the effective moratorium on approval for genetically modified organisms will be lifted by the Commission once the regulations on the approval and traceability/labelling of genetically modified foods and feeding stuffs have entered into force.
		27	The French Authorities recall their position that, before any authorization, there must be legal and technical means whereby the traceability and labelling of GMOs and GMO-derived products can be ensured.
97	GM 2-28	26	Our conclusion now is that the dossiers for the evaluation of green hearted chicory and radicchio rosso for market authorisation under Regulation 258/97 are a kind of a "never ending story". The procedure, time, energy and costs are disproportionate compared to conventional breeding programs. This may lead to the conclusion that development and marketing of transgenic vegetable crops in the European Union do not have any opportunity.

ANNEX F-2

REPLIES BY THE UNITED STATES
TO ADDITIONAL QUESTIONS POSED BY THE PANEL
IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
11 MARCH 2005

For all parties:

170. With reference to EC Directive 2001/18, Annex II, Section C.2.1, please indicate for each of the listed potential adverse effects of GMOs whether measures applied to prevent or minimise such effects fall within the scope of Annex A(1) of the SPS Agreement, and if so, why. The parties are also invited to address Section D with the same question in mind.

1. As the United States has previously noted,¹ it not necessary for the Panel to determine that every potential risk evaluated under Directive 2001/18 falls within the scope of the SPS Agreement. The Agreement makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope of the SPS agreement. Moreover, the EC has acknowledged that at least some of the potential risks that Directive 2001/18 was intended to address fall within the scope of the Agreement.²

2. Nonetheless, in the context of the products at issue in this dispute, the majority, if not all, of the endpoints referenced in Annex II C.2.1 would fall within the scope of the risks enumerated in Annex A(1) of the SPS Agreement.³

-disease to humans including allergenic or toxic effects (see e.g. items IIA(11) and IIC(2)(i) in Annex IIIA, and B(7) in Annex IIIB);

3. While the United States would not typically consider toxic and allergenic effects to be diseases, measures taken to address concerns that a biotech plant might cause disease to humans would appear to fall squarely within the scope of paragraph 1(c)—"to protect human life or health...from risks arising from diseases carried by...plants or products thereof."

4. To the extent allergenic and toxic effects are not considered to be diseases, such concerns would still fall within paragraph 1(c). Because the Directive does not address the safety from the human consumption of biotech food, the United States assumes that this relates to any toxic or allergic effects arising from occupational or residential exposures. These would be "risks to human health arising from the entry, establishment or spread of pests." As the United States has previously explained, the ordinary meaning of the term "**pest**" is "**any thing or person that is noxious,**

¹ US Answers to Questions Posed in the Context of the First Panel Meeting, Q. 49.

² EC First Written Submission, para. 433.

³ Because the Directive is intended to encompass a much wider variety of products than are relevant to this dispute (e.g., genetically modified insects or microbes), the effects listed in these sections are extremely broad, and there is consequently, some degree of ambiguity. In general, the United States has attempted to address the effects in the context of the products at issue in this dispute, rather than speculate on all of the possible adverse effects that might be encompassed within the categories, and the degree to which they might fall within Annex A.

destructive, or troublesome."⁴ Any plant responsible for causing allergic or toxic effects in any person exposed to it would certainly qualify as "destructive" or "troublesome."

disease to animals and plants including toxic, and where appropriate, allergenic effects (see e.g. items IIA(11) and IIC(2)(i) in Annex IIIA, and B(7) and D(8) in Annex IIIB);

5. This would appear to fall squarely within the scope of paragraph 1(a), irrespective of whether toxic and allergenic effects are considered to be diseases. Whether one considers the biotech plants as "disease-carrying or disease-causing" or as pests, the risks would fall squarely within paragraph 1(a) as "risks arising from the entry, establishment, or spread of pests, diseases, disease-carrying organisms, or disease-causing organisms."

effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see e.g. items IVB(8), (9) and (12) in Annex IIIA);

6. Any damage that a biotech plant could cause to population dynamics or genetic diversity would typically occur due to alterations in the invasiveness or persistence of a certain plant species, thereby causing changes in the relative abundances of different plant species that may secondarily have a negative impact on animal life. Such changes, should they occur, would be caused by the new plant species (i.e., the biotech plant), or its hybrid progeny, establishing or spreading into new areas and outcompeting and displacing wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna. As the United States has previously noted, such plants would be a weed, and thus fall within the definition of a pest, pursuant to footnote 4. Accordingly, measures taken to address such concerns would fall within paragraph 1(a), as measures taken to protect animal or plant life or health from "risks arising from the entry, establishment, or spread of pests." The intended breadth of the covered risks is confirmed by Footnote 4, which specifies that, for purposes of the definitions in Annex A, "'animal' includes fish and wild fauna; 'plant' includes forests and wild flora."

altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

7. As a general matter, based solely on the general description, this endpoint would appear to fall squarely within either paragraphs 1(a) or (c). To the extent the measure was adopted to protect animal or plant life or health, the risk would appear to arise from "the establishment of disease-carrying organisms, or disease-causing organisms," and would fall within the scope of paragraph 1(a). If, however, the concern related to human health, the measure would appear to fall within paragraph 1(c).

8. Alternatively, in the context of the products at issue, the question of whether the plant has the potential to alter the susceptibility to pathogens or to create new vectors, is something that the IPPC typically considers in determining whether an organism could be considered a pest. For example, in ISPM 11, *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms*, Annex 3 specifically include the following as potential phytosanitary risks for LMOs:

⁴ The Compact Oxford English Dictionary, Oxford University Press, 24th Printing, 1971, page 2145 (Ex. US-121).

- b. Adverse effects of gene flow or gene transfer including, for example:
- transfer of pesticide or pest resistance genes to compatible species
 - the potential to overcome existing reproductive and recombination barriers resulting in pest risks
 - potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.
- c. Adverse effects on non-target organisms including, for example:
- changes in the host range of the LMO, including the case where it is intended for use as a beneficial control agent or organism claimed to be beneficial
 - effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in an phytosanitary impact (indirect effects)
 - capacity to vector other pests
 - negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants."⁵

Consequently, these risks fall within paragraph 1(a) as risks to plant health arising from pests.

compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, e.g. by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see e.g. items IIA(11) e) and IIC((2)(i)(iv) in Annex IIIA);

9. The relevant risks described by the above paragraph would primarily relate to concerns to human and animal health arising from the presence of the antibiotic resistance marker genes in the plants.

10. As the United States has previously explained, the risks the EC has raised relating to antibiotic marker genes generally fall within paragraph 1(a). The concern described is that the antibiotic resistance gene could be transferred from the plant to a human or animal pathogen. For an animal infected with the pathogen that would ordinarily be treated with the antibiotic to which the pathogen had become resistant, the transfer of the resistance gene would contribute to the establishment and spread of disease--the disease caused by the now resistant pathogen.

11. Additionally, the antibiotic resistance gene falls within the definition of an additive under the SPS Agreement. As such, protection against any associated human or animal health risks, such as the transfer of antibiotic resistance to human or animal pathogens that the antibiotics would be used to treat, falls within paragraph 1(b).

⁵ ISPM 11, Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms, at 36 (emphasis added) (Ex. US-123).

12. The reference to "compromising plant protection treatments" also appears to indicate a concern that a biotech plant might compromise the use of various pesticide or herbicides. The most likely concern would relate to the development of pesticide resistance. As the United States has previously explained⁶, such risks would generally fall within the scope of paragraph 1(a).

effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see e.g. items IIA(11) f) and IVB(15) in Annex IIIA, and D(11) in Annex IIIB).

13. As Dr. Andow described, biogeochemical cycles relate to the environmental fate of individual chemical elements in the environment—how these chemicals, which are generally plant nutrients, cycle through the environment. These are of concern, and particularly the ones explicitly referenced above, primarily because they could affect the availability of nutrients to plants, which is relevant to plant health. In addition, changes in these cycles can indicate that there have been effects or changes in soil microorganisms. Although the experts' testimony confirmed that there is no evidence that biotech crops affect biogeochemical cycles, concerns that biotech plants might alter biogeochemical cycles would generally fall within the scope of paragraph 1(a) as risks arising from pests.

14. The Panel also requested that the parties comment on the effects listed in Annex II, section D; section D.1 applies only to "GMOs other than higher plants," and as none of the products at issue in this dispute fall within this category, there is no need for the Panel to reach this question. Section D.2, relating to the effects of higher plants, lists nine potential endpoints to be addressed as part of an environmental safety assessment.

15. Section D.2, relating to the effects of higher plants, lists nine potential endpoints to be addressed as part of an environmental safety assessment.

1. *Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.*

2. *Any selective advantage or disadvantage conferred to the GMHP.*

3. *Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species*

16. The first three points would primarily relate to the potential for the plant to become invasive or weedy. The Agreement explicitly provides that pests include weeds⁷, and measures applied to address such concerns would generally fall within the scope of paragraph 1(a) as a measure to protect plant life or health from risks arising from the entry, establishment or spread of pests. It is also theoretically possible that the risks would fall within the scope of paragraph 1(c), depending on whether the biotech plant presented a hazard to human or animal health.

4. *Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).*

⁶ US Answers to Questions Posed in the Context of the First Panel Meeting, Response to Q. 75, paras. 103-107.

⁷ SPS Agreement, Annex A, note 4.

5. *Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.*

17. These two concerns relate to direct and indirect effects on non-target organisms caused by the biotech plant. Measures taken to address such effects would generally fall within paragraph 1(a) as measures to protect animal life or health from the establishment of pests.

6. *Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).*

18. Measures taken to address any risks from occupational or residential exposure to the biotech plants would generally fall within paragraph 1(c), as measures "to protect human life or health...from risks arising from...the establishment or spread of pests." In addition, to the extent the concern relates to the presence of the *Bt* toxin/pesticidal substance in the plant, the measure would fall within para 1(b) as a "measure to protect human life from a risk arising from...a contaminant in foods."

7. *Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it if it is intended to be used as animal feed.*

19. Concerns relating to effects on animal health resulting from the consumption of feed derived from a biotech plant would generally fall within the scope of paragraph 1(b). This would also include any effects on the feed/food chain, which could relate to concerns that the biotech feed would contain contaminants or toxins that would pass through the animal and remain in the meat or milk.

8. *Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).*

20. As discussed in other responses, measures taken to address concerns that a biotech plant may adversely affect biogeochemical processes or non-target organisms, either directly or indirectly, would generally fall within paragraph 1(a).

9. *Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.*

21. These are specific examples of potential indirect effects of biotech crops, and as such, would generally fall within the scope of paragraphs 1(a) or (c), relating to risks arising from pests.

171. In Japan - Apples, the Appellate Body interpreted Article 5.7 of the SPS Agreement and notably the phrase "in cases where relevant scientific evidence is insufficient". It stated at para. 179 that:

Article 5.1 [...] informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a "more objective assessment of risks". These contextual elements militate in favour of a

link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement. [...] The question is whether the relevant evidence [...] is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.

In this regard, please answer the following questions:

- (a) Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the SPS Agreement"? Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?**
- (b) Does the phrase "more objective assessment of risks" in Article 5.7 support the view that a provisional measure adopted in accordance with Article 5.7 must be based on risk assessment, as required by Article 5.1? (Canada may wish to elaborate further on what it has already said in its supplementary rebuttal in relation to this point.)**

22. This question pertains to the relationship between the following phrases used in the SPS Agreement:

- (1) "assessment of ... risks" (Article 5.1) and "risk assessment" Annex A(4);
- (2) "cases where relevant scientific evidence is insufficient" (Article 5.7); and
- (3) "more objective assessment of risk" (Article 5.7).

23. The Appellate Body in the above quote from *Japan – Apples* explicates the relationship between (1) assessment of risk/risk assessment, as those phrases are used in Article 5.1 and Annex A; and (2) "insufficient" scientific evidence as used in Article 5.7. The key statement is as follows:

These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement.⁸

24. The first sentence in Question 171(a) above – "Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the SPS Agreement"? – is largely consistent with the Appellate Body's explication as set out above. It is important, however, to clarify that the question is

⁸ *Japan – Apples*, para. 179.

not whether the evidence is sufficient to perform a risk assessment in the abstract. Rather, the pertinent question is whether the evidence is sufficient for a Member to meet its obligation of performing a risk assessment in relation to the specific risk at issue. Or, as the Appellate Body summarized the issue above, was the evidence sufficient to perform an "adequate" risk assessment, as required under Article 5.1 and as defined in Annex A. So, for example, in light of the fact that the measure at issue in the Apples case was intended to stop the spread in Japan of fire blight (a plant disease), the Appellate Body explained that:

Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it "general" or "specific", in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.⁹

25. The second sentence in Question 171(a) above – "Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?" – is somewhat inconsistent with the Appellate Body's explication as set out above. As noted, the question is whether the evidence is sufficient for the Member to perform an adequate risk assessment, as required under Article 5.1 and as defined in Annex A. The term "fully objective risk assessment" is not used in the SPS Agreement, and the meaning of this phrase is uncertain. In addition, the second part of the above question – such that any measure based on that assessment might be maintained without sufficient scientific evidence – is incomplete. Article 5.7 applies where the scientific evidence is not sufficient for the Member to complete an adequate risk assessment, as required under Article 5.1 and as defined in Annex A. However, the measure must still be based on "available pertinent information," and the Member must also meet the additional requirements in the second sentence of Article 5.7.

26. With regard to Question 171(b), the United States does not agree that *"the phrase 'more objective assessment of risks' in Article 5.7 support[s] the view that a provisional measure adopted in accordance with Article 5.7 must be based on risk assessment, as required by Article 5.1"*. As noted above, the Appellate Body explained that "insufficient" scientific evidence, as used in Article 5.7, means "insufficient" scientific evidence for a Member to perform an adequate risk assessment, as required under Article 5.1 and as defined in Annex A. Since a precondition for the application of Article 5.7 is the insufficiency of evidence for an adequate risk assessment, it would not make sense to conclude that a provisional measure under Article 5.7 must nonetheless be based on a risk assessment (as required under Article 5.1 and as defined in Annex A to the SPS Agreement). However, a measure under 5.7 cannot be adopted on an arbitrary basis. To the contrary, Article 5.7 explicitly provides that a provisional measure must be adopted on the basis of "available pertinent information."

27. In *Japan – Agricultural Products*, the Appellate Body addressed the interpretation of "more objective assessment of risk," as used in Article 5.7:

Neither Article 5.7 nor any other provision of the SPS Agreement sets out explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what actual results must be achieved; the obligation is to "seek to obtain" additional information.

⁹ *Id.*

However, Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct "a more objective assessment of risk". Therefore, the information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied. We note that the Panel found that the information collected by Japan does not "examine the appropriateness" of the SPS measure at issue and does not address the core issue as to whether "varietal characteristics cause a divergency in quarantine efficacy". In the light of this finding, we agree with the Panel that Japan did not seek to obtain the additional information necessary for a more objective risk assessment.¹⁰

As confirmed by the above interpretation, Article 5.7 does not call for a "fully objective" risk assessment. Rather, Article 5.7 uses the term "more objective assessment" to highlight that a Member applying an Article 5.7 provisional measure has an ongoing obligation to seek to obtain more and better information that is germane to performing an adequate risk assessment, as required under Article 5.1 and as defined in Annex A.

172. Annex A(1) of the SPS Agreement suggests that "approval procedures" are SPS measures. When a Member decides to delay the completion of such an approval procedure for a number of days, would such action be another SPS measure within the meaning of Annex A(1), or would such action rather need to be characterized as an application of an SPS measure (the application of the approval procedure)?

28. This question addresses the analysis to be used under the SPS Agreement of a Member's decision "to delay the completion of an approval procedure." The United States submits that in the context of the facts and circumstances of this dispute, such a decision to delay completion of approval procedures should be analyzed both:

- (1) under the provisions of Annex C, including the "undue delay" provision of Annex C(1)(A); and
- (2) as a distinct SPS measure that must be consistent both with the obligations in Annex C of the SPS Agreement and with the obligations outside of Annex C, including the obligations in SPS articles 2.2, 2.3, 5.1, 5.5 and 7.

29. Annex C Obligations: Article 8 of the SPS Agreement provides that "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures ...".¹¹ A decision to delay the completion of an approval procedure fits squarely within Article 8's disciplines on the "operation of ... approval procedures," including the "undue delay" discipline in Annex C(1)(a).

30. SPS Obligations Outside of Annex C, including Articles 2.2 and 5.1: The United States has not contended that a decision to delay the completion of an approval procedure for a particular product for a day, or a week, would amount to a distinct SPS measure that requires analysis of SPS obligations outside of Annex C.¹² Rather, the United States submits that a decision to delay completion of approval procedures for biotech products for an indefinite period of time – in this case

¹⁰ *Japan – Agricultural Products*, AB-1998-9, para. 92 (emphasis added).

¹¹ Question 172 uses the phrase "application of an approval procedure." Given the text of SPS Agreement Article 8, perhaps a more precise phrasing would be "operation of an approval procedure."

¹² Such delays in the operation of approval procedures would, of course, have to be consistent with the "undue delay" obligation in Annex C(1)(A).

from late 1998 up through at least August 2003 – and which consequently has the effect of preventing the sale or marketing of new biotech products – amounts to both a single distinct SPS measure (the general moratorium) and separate distinct SPS measures for each covered product (the product-specific moratoria) and that these measures must meet obligations outside of Annex C.¹³ The reasoning is straightforward: a decision to delay approval procedures for an indefinite period is effectively equivalent to decision to adopt bans on the import and marketing of all products subject to the approval procedure. The requirement that product bans must, for example, not be "maintained without sufficient scientific evidence"¹⁴ lies at the core of the object and purpose of the SPS Agreement.

173. May the fact that existing approval legislation does not permit a Member to adopt certain risk management measures which that Member considers appropriate serve as a justification, for purposes of an analysis under Annex C(1)(a) of the SPS Agreement, for delaying approval procedures conducted pursuant to the existing legislation? Are the provisions of Article 27 of the Vienna Convention on the Law of Treaties relevant to such a situation?

31. As an initial matter, the United States notes that it does not accept the premise that any delays in the EC's processing of biotech applications were due to any need by the EC to adopt additional legislation authorizing new or different risk management measures. In fact, this premise is directly contrary to the EC's own contention that it adopted an "interim approach" in 2000, under which products could be considered and approved under the legal authority of Directive 90/220 while applying the (allegedly different) standards of Directive 2001/18 (which did not enter into force until 2003).¹⁵ Furthermore, the EC has denied that the EC delayed all final decisions on biotech approvals until the April 2004 entry into force of the GM Food and Feed and Traceability and Labelling legislation.

32. As the United States has explained previously, questions of "undue delay" must be determined on the basis of the facts and circumstances of any particular delay. In this case, the EC has not shown that the moratorium lasting from October 1998 through at least August 2003 was justified by any purported need for additional legislation (nor has the EC shown that the moratorium was justified for any other reason). Likewise, the EC has not shown that any particular delays in processing applications were delayed by any purported need to await new legislation.

33. Although questions of "undue delay" must be addressed on a case-by-case basis, there is an important legal principle that is implicated by the Panel's question: the United States submits that a Member's supposedly inadequate legislation cannot *excuse* a member from its obligation under Annex C(1)(A) to undertake and complete approval procedures without "undue delay." A finding to the contrary would render the "undue delay" obligation a nullity: a Member could avoid the obligation to undertake and complete approval procedures without "undue delay" simply by failing to take the steps necessary under its domestic law to adopt the necessary legislation.

¹³ See First US Submission, sections IV(b)(1)(f), (g), (h), and (i) (discussion of general moratorium) and IV(b)(2)(e),(f), and (g) (discussion of product-specific moratoria).

¹⁴ SPS Agreement, Article 2.

¹⁵ EC Answers to First Set of Questions, para. 35. Furthermore, as Canada explained in Part II.B.1 of its Second Written Submission, the EC has entirely failed to show that Directive 2001/18 was adopted for the purpose of authorizing additional risk management measures.

34. An analogy to provisional measures under Article 5.7 is also instructive.¹⁶ A decision by a Member to suspend approval procedures until the Member adopts new legislation has an effect equivalent to the adoption of a provisional ban on all new products covered by those procedures. When the drafters of the SPS Agreement considered provisional bans, the only circumstance included in Article 5.7 for the adoption of provisional measures is "in cases where relevant scientific evidence is insufficient." If inadequate legislation were also considered to be a justification for the adoption of provisional measures, Article 5.7 could have stated "in cases where relevant scientific evidence or domestic legislation is insufficient." But, of course, Article 5.7 includes no such statement.

35. With regard to Article 27 of the Vienna Convention on the Law of Treaties, the United States agrees that the *principle* set out in Article 27 – namely, that "A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty" – is relevant for a consideration of whether inadequate domestic legislation excuses a Member from its WTO obligations. The United States submits, however, that the principle in Article 27 is already fully reflected in the text of the WTO Agreement and is confirmed in Appellate Body reports. Accordingly, there is no need to turn to general principles of international law in order to support a finding that inadequate domestic legislation does not excuse a WTO Member from its WTO obligations.

36. The text of the SPS Agreement explicitly states that SPS measures include "all relevant laws,"¹⁷ and the Agreement sets out specific obligations with regard to those measures (including a Member's domestic laws). By imposing obligations on "all relevant laws" of a Member, the Agreement is clear that inadequate laws cannot serve as an excuse for non-performance of SPS obligations.

37. In addition, in one of its first reports – *US – Reformulated Gasoline* – the Appellate Body confirmed that a WTO Member is responsible for the actions of its legislative branch. In that case, the United States explained that it had adopted the measure at issue (a measure found to be inconsistent with GATT Article III) because of "difficulties of verification and enforcement." The Appellate Body agreed with the Panel that cooperative, non-discriminatory measures were available to overcome those difficulties. The Appellate Body acknowledged that such cooperative measures required the US Congress to provide funding, but explained that "of course" this fact did not excuse the United States from compliance with its GATT obligations:

The fact that the United States Congress might have intervened, as it did later intervene, in the process by denying funding [for the cooperative verification and enforcement measures], is beside the point: the United States, of course, carries responsibility for actions of both the executive and legislative departments of government.¹⁸

38. In sum, even if the EC could show that it adopted the moratorium and delayed product applications in order to await the legislative enactment of revised SPS legislation, this showing could not justify a five-year moratorium and resulting delays, or otherwise bring the measure into compliance with the EC's obligations under the SPS Agreement. The principle that inadequate legislation does not justify a Member's noncompliance with WTO obligations is plainly reflected in the text of the WTO Agreement and is confirmed in Appellate Body reports.

¹⁶ As noted in response to the Panel's Question No. 125, the United States considers that Article 5.7 can serve as relevant context to be examined in deciding how to apply the "undue delay" provision of Annex C.

¹⁷ SPS Agreement, Annex C(1).

¹⁸ *United States - Standards for Reformulated and Conventional Gasoline*, AB-1996-1, at 27.

174. With regard to Article 2.2 of the TBT Agreement:

- (a) Please explain the phrase "the risks non-fulfilment [of a legitimate objective] would create" and illustrate using an example.**
- (b) Article 2.2 refers to "scientific information" which must be taken into account in assessing risks. Article 5.2 of the SPS Agreement, on the other hand, refers to "scientific evidence". Are these different concepts? Why?**

39. As the United States has previously shown, and as the EC does not contest, each measure at issue in this dispute was adopted for at least some reasons covered within the scope of the SPS Agreement. This fact brings the measures within the scope of the SPS Agreement, and – pursuant to Article 1.5 of the TBT Agreement¹⁹ – the TBT Agreement does not apply to the measures at issue. Accordingly, the United States respectfully submits that the Panel need not engage in an analysis under the TBT Agreement of the measures at issue.

175. Are measures applied to ensure co-existence of biotech crops and non-biotech crops covered by Annex A(1) of the SPS Agreement or do they fall, in whole or in part, outside of the scope of Annex A(1)?

40. As an initial matter, the United States notes that the EC has not shown or even claimed that any measures at issue in this dispute are applied solely to ensure "co-existence" of biotech and non-biotech crops. The EC has denied even the existence of the general and product-specific moratoria, and the EC has conceded that each of the member State measures was adopted for at least some reasons that the EC agrees are covered within the scope of the SPS Agreement.

41. Also, the United States notes that the concept of "co-existence" is not well-defined. Accordingly, the analysis of whether any particular "co-existence" measure would fall within the scope of the SPS Agreement would turn on the details of the particular measure.

42. However, the United States would make the following two points on the application of the Annex A definition of an SPS measure to a hypothetical EC measure addressed only to "co-existence." In the event that the entry, establishment or spread of a biotech crop created a risk of damage to other crops (be they other biotech or non-biotech crops) – by, for example, reducing the quality of such other crops – such risks would be covered by either Annex A(1)(a) (covering risks to plant life or health) or A(1)(d) (covering other damage within the territory of a Member). It should be noted that the United States is not aware of any evidence that the entry, establishment, or spread of a biotech crop poses the risk of causing such damage.

43. The United States has serious concerns, however, with the notion that merely mixing biotech crops with non-biotech crops could amount to a "risk to plant life or health" or to "other damage" – either as a matter of fact, or for purposes of applying Annex A(1) of the SPS Agreement. Every time any new crop variety is introduced into a Member, there are possibilities that the new varieties will mix with existing varieties by mechanisms such as cross-pollination, delayed germination of the new seeds in fields subsequently used for existing varieties, and mixing in handling and transportation facilities. The United States understands that such mixing normally would not cause "damage" to

¹⁹ "The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures." TBT Agreement, art. 1.5.

either the new varieties or to the existing varieties. The United States would need to evaluate carefully any EC argument to the contrary.

For Argentina, the United States and the European Communities:

176. With reference to Austria's safeguard measure on Bt-176 maize, please comment on the reference in exhibit EC-158 att. 7 to insufficient labelling requirements laid down in the Commission Decision relating to the relevant product. In particular, what is the basis for the concern expressed about insufficient labelling (e.g., food safety, consumer information, etc.), and how does the labelling issue affect the analysis of whether the Austrian safeguard measure falls within the scope of the SPS Agreement and/or the TBT Agreement?

44. The Austrian reference to insufficient labeling requirements is unclear. Since Regulation 258/97 already included a labeling requirement for biotech foods,²⁰ Austria's concern is particularly puzzling.

45. Based on Austria's statement in the cover note, Austria's rationale for labeling may relate solely to the provision of information about the method used to produce BT-176 maize, and may not have any purported rationale based in food safety. On the other hand, the accompanying memorandum also refers to a concern that biotech corn seed will be bred, and that subsequent progeny will not be labeled, even though they contain antibiotic resistance marker genes.²¹ To the extent this was intended to express a concern that the products should be labeled to communicate a potential risk from the presence of the antibiotic marker, the concern would fall within the scope of the SPS Agreement—either pursuant to subparagraph 1(a) or (c), depending on the precise nature of the concern.

46. But ultimately, the reference to concerns regarding the adequacy of labeling does not affect the conclusion that Austria's safeguard measure falls within the scope of the SPS agreement. As outlined in the accompanying eight-page memorandum, the Austrian safeguard measure was adopted to address concerns relating to human and animal health risks arising from the presence of the antibiotic resistance marker gene in the plant, and concerns relating to the development of insect resistance to the Bt toxin. As previously discussed, these concerns fall within the scope of the SPS Agreement—under Annex 1(a) or (b) and under subparagraph (c).

For the United States and the European Communities:

177. At para. 336 of Canada's first written submission and paras. 570 and 544-545 of Argentina's first written submission, the allegation is made that certain member State safeguard measures are inconsistent with Article 2.1 of the TBT Agreement because imported biotech products subject to the safeguard measures are treated less favourably than like domestic non-biotech product varieties which may be sold freely in the relevant member States. Do the United States and the European Communities share the interpretation of the concept of less favourable treatment underlying Argentina's and Canada's claims? In answering this question, please discuss the relevance of para. 100 of the Appellate Body report on EC - Asbestos. If it is relevant, could the United States and the European Communities (a) indicate whether they agree with the interpretation offered at para. 100, and (b) explain in detail how this interpretation could be applied in practice?

²⁰ Regulation 258/97, Article 8(d).

²¹ EC Exhibit 158, att. 7, p. 8.

47. The United States respectfully refers the Panel to the US response to Question 174 above.

For all complaining parties:

178. Please indicate whether the following alleged effects of biotech products fall within any of the subparagraphs of Annex A(1) of the SPS Agreement:

- (a) **Environmental components of biodiversity "outside human, animal or plant life or health, such as the ecological complexes referred to in the Convention on Biodiversity" (EC rebuttal, para. 266).**

48. It is unclear what effects the above phrase would encompass that would be relevant to the products at issue in this dispute. A biotech plant can only damage biodiversity or the ecological balance of an area through its ability to adversely affect, directly or indirectly, the wild flora or fauna of the area. And as the United States has previously explained, such effects are generally covered by paragraph 1(a), as risks to animal or plant life or health "arising from the entry, establishment, or spread of pests."

49. To the extent this phrase is intended to address the health of the entire web of life in a particular environment--such as the ecological relationship among plants and animals, apart from the life or health of individual plants and animals--this ultimately does relate to life and health of the members of the individual species within that web, such that a particular species or subtype within a species in a particular environment would not survive.

50. Moreover, the pertinent question is not whether the SPS agreement covers every conceivable environmental risk, but whether the risks that the EC has raised with respect to the products at issue in this dispute, either in whole or in part, fall within the scope of the SPS Agreement. And as the United States has previously explained, the text of Annex A clearly encompasses the full range of adverse environmental effects that a biotech plant might present.

51. Any damage that a biotech plant might cause to biodiversity or the ecological balance of an area would typically occur due to alterations in the invasiveness or persistence of a certain plant species, thereby causing changes in the relative abundances of different plant species that may secondarily have a negative impact on animal life. Such changes, should they occur, would be caused by the new plant species (i.e., the biotech plant), or its hybrid progeny, establishing or spreading into new areas and outcompeting and displacing wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna. Further, to the extent the issue relates to concerns regarding direct or indirect effects on non-target organisms, the measure would generally fall within the scope of paragraph 1(a).

- (b) **"A predator insect eating another insect because it is itself growing better on a diet of Bt maize" (EC rebuttal, para. 266).**

52. This hypothetical effect is simply a specific example of a possible indirect effect of a *Bt* crop. To the extent the crop is either directly or indirectly responsible for an adverse ecological effect, it would fall within the definition of a pest. Measures taken to address risks arising from pests fall squarely within Annex A.

- (c) **Human health risks arising from occupational exposure to a substance in a biotech product that is a toxin for insects (e.g., the Bt toxin) as opposed to risks arising from the consumption of the biotech product (EC rebuttal, para. 316).**

(The United States may elaborate on its response to Panel Question 73 or comment on the European Communities' response).

53. As the United States originally noted in its response to Panel Question 73, given that footnote 4 clearly identifies pesticide residues as contaminants, such a measure would fall within the scope of paragraph A(1)(b). In this regard, it should be noted that paragraph A(1)(b) is not limited to the risks from the "consumption" of contaminants in foodstuffs.

54. In addition, as the United States has noted above in response to these questions, measures taken to address risks from occupational or residential exposure to the biotech plants would generally fall within paragraph 1(c), as measures "to protect human life or health...from risks arising from...the establishment or spread of pests."

179. Please comment on the European Communities' statement that "for the purposes specifically of proving a 'moratorium' that applies across the board, it does not suffice to address only a limited selection of product applications" (EC rebuttal, footnote 212).

55. The EC's argument is without merit, and based on two false premises.

56. The first false premise is that the complainants have defined the general moratorium as a decision to suspend all processing of all applications, regardless of where those applications stand in the EC's complex approval process. However, as the complainants have explained repeatedly, the general moratorium was a political decision to prevent any products from reaching the final stage of approval. Thus, nothing in the theory of the US case requires an examination of each and every delay for each and every product. Moreover, the fact that some applications made some progress in the EC's complex approval procedures is entirely consistent with the adoption of a general moratorium on final approvals.

57. The second false premise is that the complainants "address only a limited selection of product applications." This is untrue: the United States has shown that no biotech product application under consideration in the period October 1998 to August 2003 completed the EC's community-level approval procedures.²² (Indeed, the EC does not even contest this fundamental fact.) Because the complainants assert that the general moratorium was a decision not to allow any product to reach the final stage of the approval process, a showing that indeed no product reached a final decision is precisely the evidence the complainants needed to support complainants' contention that the EC adopted a general moratorium.

For Canada and the United States:

182. Could Canada and the United States provide examples of why and how allergens in food can be said to "destroy[] life or injure[] health" (US rebuttal, attachment II, para. 27) or "destroy[] life or impair[] seriously the functions of organs or tissues" (Canada's supplementary rebuttal, para. 51)?

58. An allergen present in food can cause a variety of symptoms in individuals allergic to that allergen. Some examples of food allergic reactions include angioedema (swelling and redness of the skin), urticaria (itchy hives), allergic rhinitis (runny nose), asthma, and anaphylaxis (a sudden and

²² First US Submission, Part III.C.1.

severe reaction characterized by a sudden drop in blood pressure and breathing difficulties that may be fatal).²³

For the United States:

191. In relation to antibiotic marker genes, please answer the following questions:

- (a) **With reference to para. 22 of attachment II of the US rebuttal and Codex standard 192, (i) what is the "technological purpose" for which antibiotic marker genes are added to food and (ii) in what way does the antibiotic marker gene become a "component" or "otherwise affect the characteristics" of the food to which it is added?**

59. (*Question 191(a)(i)*): Antibiotic resistance marker genes are used in the development of biotech food crops. They aid the developer in isolating and amplifying the gene of interest, so that the gene of interest can be introduced into the plant. In some cases, it may also be used to isolate plant cells that have incorporated the newly introduced gene of interest. Those plant cells are then used to generate the bioengineered plant. Thus, the technological purpose of antibiotic resistance marker genes is to aid in the manufacture of the food from the biotech plant.

60. (*Question 191(a)(ii)*): The marker gene becomes a part of the DNA of the plant, and of food from the plant. Thus, it is a component of the food from the plant, the addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component or otherwise affecting the characteristics of such foods.

- (b) **Please comment on the European Communities' assertion that "there is concern about the development of antibiotic resistance in connection with 'plants' as such" (EC rebuttal, para. 64) and on whether a measure applied to address this concern would fall within the scope of Annex A(1).**

61. As noted in answer to 191(a)(i) above, an antibiotic resistance marker gene can be considered an additive in foods and feedstuffs, under Annex A(1)(b), and as such, measures applied to address risks in foods and feedstuffs from such marker genes is covered under Annex A(1). Whether the European Communities believes that antibiotic resistance marker genes pose additional risks in "plants as such," and whether those risks are or are not covered by the SPS Agreement, in no way alters the fact that risks posed by antibiotic resistance marker genes include risks covered by the SPS Agreement.

62. However, we would note that the main (if not only) risk that can be posed by "the persistence of plant-derived DNA in the environment during crop cultivation and harvesting, and in soil residues," (EC rebuttal, para. 64) such that there could be "concern about the development of antibiotic resistance in connection with "plants" as such" (EC rebuttal, para. 64) is that resistance will pass to microbial pathogens that would otherwise be treatable by the antibiotic at issue if the pathogens should infect and cause disease in humans or animals. As noted by the food safety expert to the panel, there is no evidence that such transfer occurs at a biologically significant rate so as to pose a real risk

²³ Additional information on food allergy and its impacts on human health can be found in HA Sampson. Food allergy Part 1: Immunopathogenesis and Clinical Disorders, *J Allergy Clin Immunol* 1999; 103:717-28, attached to these responses as Exhibit US-149.

to life or health of plants or animals. However, whatever risk is posed would be posed similarly from food on the plant and from parts of the plant that are not used as food. We would further note that animals eat almost all parts of the crops at issue in this dispute. Therefore, there is little real distinction for the purposes of this discussion between "plants as such" and "food from plants."

192. With reference to paras. 16 and 17 of the US supplementary rebuttal, please clarify whether a measure applied to protect against risks to wild fauna from increased use of the herbicide associated with a biotech crop or another herbicide, due to the development of herbicide resistance, falls within the scope of Annex A(1) of the SPS Agreement. If so, please indicate the relevant subparagraph.

63. A measure applied to protect against risks to wild fauna from increased use of an herbicide in the circumstances described above would fall within the scope of Annex A(1), subparagraph (a)—a measure to protect "animal ... life or health ... from risks arising from the entry, establishment, or spread of pests."

64. In the circumstances described in paragraphs 16 and 17 of the US rebuttal, the pest against which the measure was directed would be the herbicide resistant crop. As previously explained, the phrase, "arising from" does not require that the risk be direct or immediate. The critical question is whether the risk results from the presence of the organism, and in the scenarios described in paragraphs 16 and 17, the risks "arise from" the organism in that it is the presence of the organism that triggers the necessary sequence of events. Here, the herbicide resistant crop would ultimately be responsible for any increased potential for risks to animal life or health that resulted from either the increased use of an herbicide, or the application of a more toxic alternative, because the herbicide-resistant crop would have been responsible for the need to apply the additional herbicide.

193. With reference to paras. 62 and 63 of the US supplementary rebuttal, did the United States submit evidence that the UK supported the alleged moratorium at the time it completed its initial assessment of GA21? If not, what is the basis for the assertion that the alleged inaction by the UK was "politically motivated"?

194. With reference to paras. 52 and 59, 102-103, 159, 168 and 195-196 of the US supplementary rebuttal, did the United States submit evidence that the Netherlands supported the alleged moratorium at the time at issue in the aforementioned paragraphs?

195. With reference to paras. 72, 95, 150-151 and 190 of the US supplementary rebuttal, did the United States submit evidence that Spain supported the alleged moratorium at the time at issue in the aforementioned paragraphs?

65. (*Combined response to questions 193, 194, and 195*): In its prior submissions, the United States has submitted overwhelming evidence of the existence of the de facto moratorium. Such evidence consisted of, *inter alia*, statements from EC member States and EC officials that openly acknowledged a general moratorium on the approval of biotech products. And, as the United States has detailed in its prior answer to Panel's question 151, the EC's own evidence provide numerous additional examples of EC member States confirming the existence of the moratorium. That evidence includes numerous examples of countries other than the above five "moratorium countries" acknowledging the moratorium and even stating their support for the moratorium. For example, EC Exhibit 92, attachment 24_trans, provides:

In the German Government's view, the effective moratorium on approval for genetically modified organisms will be lifted by the Commission once the regulations

on the approval and traceability/labelling of genetically modified foods and feeding stuffs have entered into force.

66. Spain likewise recognized the moratorium. For example, in EC Exhibit 73, attachment 12, the Spanish authority stated: "Sin embargo, en el año 1999 se votaron ambos expedientes y no se alcanzó la mayoría cualificada, quedando pendientes y paralizados durante la moratoria de facto."

67. Such statements against interest are particularly compelling evidence. In this regard, at least Austria, France, Belgium, Germany, Spain, Italy, Luxembourg, Denmark, Sweden, and the Commission have all made statements or made reference to the fact that a moratorium existed. As the United States said in its oral statement at the second substantive meeting of the panel, it is only in the context of this case that the EC denies the existence of a moratorium.

68. In its supplementary rebuttal, the United States has complemented this core evidence with further examples, culled from the information submitted by the EC during the course of this proceeding, of various actions by member States that resulted in undue delay, were wholly consistent with the moratorium, and reflected the impact of the moratorium. When assessed within the context of all the prior evidence Complainants have already provided, these numerous examples of unexplained delays and gaps across the spectrum of biotech applications, and of unjustified requests for additional data, serve to further confirm the moratorium's existence and to confirm that biotech applications were unduly delayed. As the United States stated in its supplementary rebuttal, once the EC had made a political-level decision to adopt a moratorium on biotech approvals, EC and member State regulators understandably were in no hurry to process pending biotech applications.

69. Thus, for example, in paragraphs 62 and 63 of its supplementary rebuttal, the United States pointed out a 7 *month* delay by the UK competent authority in forwarding the application on to the Commission after the UK authority had reached a positive safety assessment on the product at issue. Many EC member States, including the UK, are divided internally on their position related to biotechnology. On the one hand, elements of the UK government have been supportive of agricultural biotechnology. On the other hand, certain political figures are not supportive. In particular, the UK Environment Minister at the time of the delay in question was Michael Meacher, and Mr. Meacher was and is strongly opposed to the introduction of genetically modified foods in the UK.²⁴ Thus, such examples show that countries other than the "moratorium countries" allowed the moratorium to continue, recognized its political reality, and that this reality at times affected the manner in which they conducted their assessments of biotech applications.

196. With reference to para. 38 of the European Communities' second oral statement, does the United States agree that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open, such that a competent authority would be justified in awaiting the outcome of the missing assessment?

70. No, the United States does not agree.²⁵ The general approach to assessing the safety of a new plant variety developed through biotechnology is to perform a molecular characterization, a safety

²⁴ See attached Exhibit US-150 (article by Mr. Meacher comparing his anti-biotech stance with the more pro-biotech stance of "the Prime Minister, ministers on the relevant cabinet sub-committee, Defra officials, and the Government's chief scientific advisers.")

²⁵ The United States also notes that the above assertion by the EC appears to be inconsistent with the EC's positions as stated during the meeting with the experts. In particular, at the experts' meeting, the United States understood the EC to be asserting that a *de novo* safety evaluation of hybrids was necessary even if the parental lines had been favorably assessed.

assessment of any newly expressed substances, and compositional analysis. The compositional analysis consists of a comparison of the levels of key compositional components (e.g., key nutrients, key anti-nutrients, and key toxicants) of the new variety with those of conventional varieties of the same crop. One way that is often done is to compare the composition of the new variety with that of its parents. However, if the safety of one or both of the parental varieties has not been established for use as a comparator, one might use other closely related lines. For example, para. 44 of the Codex Plant Guideline (CAC/GL 45-2003) states: "The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen."

197. For the purposes of demonstrating the existence of the European Communities' alleged failure to consider specific biotech products for approval ("product-specific moratoria"), is the United States seeking to rely on the evidence and argument adduced in support of the existence of a general moratorium? In other words, is the United States arguing that the existence of a general moratorium necessarily implies the existence of product-specific moratoria? Please clarify.

71. The United States submits that the EC has adopted a general moratorium on biotech approvals, under which no biotech application was allowed to reach final decision up through August 2003 (the time of the establishment of the Panel). Since the general moratorium applied to all products, a necessary corollary is that the EC also adopted product-specific moratoria on each of the product applications covered in the US panel request.²⁶ Thus, the evidence and arguments that the United States adduced in support of the existence of a general moratorium also establish the existence of the product-specific moratoria, and that the EC did not undertake and complete its approval procedures for each individual product without "undue delay."

72. In addition, the evidence and arguments adduced by the United States include examples of unwarranted delays in the processing of particular applications,²⁷ as well as delays specifically arising from scientific questions posed by member States that were not required for completion of the EC's approval procedures.²⁸ Such evidence and arguments, like the non-product-specific evidence and arguments adduced by the United States, serves two purposes. First, the showing of particular, product-specific delays is further confirmation of the existence of the general moratorium, and rebuts the EC's contention that all applications subject to the moratorium were processed normally and without undue delays. Second, the showing of particular, product-specific delays provides further confirmation of the existence of the product-specific moratoria, and establishes specific instances of "undue delay" for those particular products.

²⁶ As the United States noted previously, the United States is not requesting findings on the product-specific moratoria for applications that were withdrawn prior to the establishment of the Panel in August 2003.

²⁷ See, e.g., US Rebuttal Submission, Part V.A; US Supplementary Rebuttal, Part III.

²⁸ See US Supplementary Rebuttal, Part IV.

ANNEX F-3

COMMENTS BY THE UNITED STATES ON THE REPLIES OF THE EUROPEAN COMMUNITIES TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING 18 MARCH 2005

1. The United States appreciates this opportunity to comment on the EC's responses to the questions posed by the Panel in connection with the second substantive meeting. Many of the points raised by the EC have already been addressed by the United States in prior oral and written submissions, or are not relevant to the resolution of this dispute. In the responses below, the United States will focus on new points raised by the EC that are pertinent to the resolution of this dispute and which have not been addressed in prior US submissions.

For all parties:

119. With reference to exhibit US-123 (reproduced at para. 9 of attachment II of the US rebuttal), do the references in ISPM 11 to "indirectly affect plants ... by other processes such as competition" (page 34) and "significant reduction, displacement, or elimination of other plant species" (page 19) support the view that the term "injurious" in the IPPC definition of "pest" ("any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products") should be given a broad interpretation?

2. Generally, the EC responses that concern the scope of the SPS agreement present few issues that have not already been fully addressed in previous filings. Of these, the United States will focus primarily on two overarching points, before addressing some of the individual arguments.

3. First, the EC acknowledges that many of the risks alleged to be relevant to this dispute fall within the SPS agreement.¹ Consequently, the Panel does not need to engage in a sweeping examination of whether every risk the EC has raised falls within the scope of the SPS Agreement. The SPS Agreement explicitly provides that "any measure" applied to protect against one of the enumerated risks falls within its scope. The Agreement does not require that an SPS measure be exclusively applied to protect against enumerated risks.

4. The second point relates to the EC's repeated attempts to confuse the question before the Panel by arguing that "biodiversity and environmental issues do not fall within the scope of the SPS agreement."² This argument attempts to create an artificial distinction between effects on the environment and biodiversity in the abstract, and the specific effects on biodiversity and the environment that the EC has alleged are relevant to the products at issue in this dispute.

5. While it is clear that, as a general matter, the text of the Agreement does not support the EC's categorical exclusions of "risks to biodiversity and the environment," the Panel need not reach the question of whether the SPS Agreement covers all environmental risks to resolve this dispute. Even assuming some need to examine whether individual risks fall within the scope of Annex A, the pertinent question is whether the risks the EC has identified as relevant to this dispute, based on the characteristics of the products at issue, fall within the risks in Annex A, not whether the SPS Agreement generally covers every conceivable environmental risk. Thus, for example, the Panel need

¹ EC Answers of March 11, 2005, paras. 1-52.

² EC Answers of March 7, 2005, para. 8.

not find that all risks to non-target organisms are necessarily covered under the SPS Agreement in order to conclude that any risks to soil microorganisms from a biotech plant falls within the ordinary meaning of a risk to animal or plant life or health from a pest, pursuant to Annex A.1(a).

6. Accordingly, the Panel should only consider the facts presented in this dispute, not the hypothetical facts the EC has presented. As the United States has previously explained, the specific environmental effects that the EC has raised fall within the scope of Annex A.³ And as discussed more specifically below, none of the EC's responses effectively rebuts this conclusion.

7. A central flaw in the EC categorization of risks is the EC's inconsistent and illogical treatment of IPPC and Codex definitions. As the United States has explained, the Panel is to interpret the Agreement "in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."⁴ The United States has also explained that definitions in Codex and IPPC documents may be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement, but that IPPC and Codex definitions cannot control the interpretation of the Agreement. Thus, the point is not that environmental issues fall within the SPS Agreement because ISPM 11 addresses environmental risks. Rather, the point is that the ordinary meaning of the SPS Agreement encompasses the specific risks that the EC has alleged to be relevant—for example, because the term "pest" encompasses organisms that pose both direct and indirect risks. Consequently, for example, measures adopted to address risks to animal or plant health arising from changes in the biogeochemical cycles, as a result of the biotech plant, would fall squarely within Annex A.1(a).

8. With respect to the EC's use of IPPC and Codex definitions, however, no logical, consistent underlying principle can be discerned from the EC's responses. For example, the responses simultaneously argue that the Panel is, in some cases, bound by a subset of the IPPC definition: "If a GMO crop adversely affects the biogeochemical cycle, for example, it is simply not behaving as a "pest" within the meaning of the IPPC—and in this respect the European Communities also refers to its answer to question 119. These matters therefore fall outside the scope of the SPS Agreement."⁵ Yet in other cases, the EC argues it would be "legal error to simply transpose [the IPPC] definition [of a pest] into Annex A.1 of the SPS Agreement."⁶

9. In yet other responses, the EC argues that the Panel may consider "parts of [Codex and IPPC standards as] relevant context."⁷ However, the sole basis the EC articulates for how the Panel is to determine the "parts" that provide relevant context appears to be whether the EC has any "particular difficulty" with the standards.⁸

10. In its most recent submission, the EC raises several objections to consideration of ISPM 11, attempting to discount the fact that the IPPC's interpretation of the term "pest" contradicts the EC's attempts to rely on the IPPC definition of a pest to support its categorical exclusions. These include the arguments that ISPM 11 (rev. 2) should be rejected because (1) it post-dates the Panel's establishment, and (2) that the environmental risks described in ISPM 11 were merely "designed to reflect the Biosafety Protocol." The EC is wrong on both counts.

³ US Rebuttal Submission, Attachment II; Responses of the United States to the Questions by the Panel Posed During and After the Second Substantive Meeting with the Parties; Responses of the United States to the Additional Questions Posed by the Panel on March 4, 2005.

⁴ Vienna Convention on the Law of Treaties, Article 31(1).

⁵ EC Answers of March 7, 2005, para. 57.

⁶ EC Answers of March 7, 2005, para. 5.

⁷ EC Answers of March 7, 2005, para. 91 (emphasis added); see also para. 5.

⁸ EC Answers of March 7, 2005, para. 5, 91.

11. First, with regard to the timing of the IPPC document, the IPPC also articulated the interpretation that the term "pest" applies to organisms that have indirect effects on plants in ISPM 11, Rev 1, Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risk in April 2003, prior to the date the Panel was established. Annex 1 of that document reads:

"COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO ENVIRONMENTAL RISKS

"The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of plant pests includes weeds and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms which are pests because they:

- *directly affect uncultivated/unmanaged plants*

Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease (*Ophiostoma novo-ulmi*)

- *indirectly affect plants*

In addition to pests that directly affect host plants, there are those, like most weeds/invasive plants, which affect plants primarily by other processes such as competition (*e.g.*, for cultivated plants: Canada thistle (*Cirsium arvense*) [weed of agricultural crops], or for uncultivated/unmanaged plants: purple loosestrife (*Lythrum salicaria*) [competitor in natural and semi-natural habitats]).

- *indirectly affect plants through effects on other organisms*

Some pests may primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents."⁹

12. Similarly, the IPPC document elsewhere makes clear that part of the evaluation of whether an organism is a quarantine pest includes consideration of both an organism's direct and indirect effects.¹⁰ For example, section 2.3.1.1 "Direct pest effects," provides:

"In the case of the analysis of environmental risks, examples of direct pest effects on plants and/or their environmental consequences that could be considered include:

- reduction of keystone plant species
- reduction of plant species that are major components of ecosystems (in terms of abundance or size) and endangered native plant species (including effects below species level where there is evidence of such effects being significant)

⁹ ISPM 11, Rev 1, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risk* (2003), p. 29 (Ex. US-151).

¹⁰ ISPM 11, Rev 1, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risk* (2003), pp. 18-20 (Ex. US-151).

- significant reduction, displacement or elimination of other plant species

The estimation of the area potentially endangered should relate to these effects."

13. The EC also has no basis for its second argument – that the environmental risks described in ISPM 11 were merely "designed to reflect the Biosafety Protocol." In fact, the earlier, 2003 version of ISPM 11 (rev. 1) did not even specifically address biotech organisms. Accordingly, there is no reason to believe that ISPM 11's inclusion of an organism's direct and indirect effects on the environment related to the adoption of the Protocol.

120. With reference to Annex A(1)(d) of the SPS Agreement, please answer the following questions:

- (a) What is the meaning of the term "other damage"?**
- (b) Does the term "other" imply that Annex A(1)(a) through (c) are also about "damage"? If so, does the term "other damage" cover damage sustained by plants, animals or humans other than damage to their "life or health"? Please provide examples.**
- (c) Is "other damage" limited to damage sustained by plants, animals or humans? If not, please provide examples.**

14. In its answer to Question 120, the EC again makes the unsupported – and unsupportable – assertion that "environmental damage is not covered by the SPS Agreement."¹¹ As the United States previously explained, the SPS Agreement contains no such exclusion of environmental damage. To the contrary, SPS Agreement specifically provides that for purposes of the definitions in Annex A, "'animal' includes fish and *wild fauna*; [and] 'plant' includes forests and *wild flora*."¹²

15. In its answer, the EC for the first time cites to a late 1990 draft text of the SPS Agreement, and argues that the changes from that draft to the final SPS text supports the EC's view regarding a purported exclusion of environmental damage. As an initial matter, the United States notes that where, as here, the text of the agreement explicitly covers damage to wild flora and fauna, there is no ambiguity and thus no need to examine negotiating history on whether damage to wild flora and fauna is covered within the scope of the SPS Agreement.¹³ That said, the EC's citation to the negotiating history is incomplete and misleading, and in no way supports the EC's contention.

16. The EC's citation to the late 1990 draft text includes no footnotes, document numbers, or exhibits.¹⁴ However, based on the quotations in the EC submission, the EC is apparently referring to "Negotiating Group on Agriculture: Working Group on Sanitary and Phytosanitary Regulations and Barriers; Draft Text on Sanitary and Phytosanitary Measures," MTN.GNG/NG5/WGSP/7 (20 November 1990). The cover note to this document does include the following language quoted by the EC: "the brackets in the note to definition 1 and in definition 4 (Annex A) are all linked to the

¹¹ EC Answers of March 7, 2005, para. 21.

¹² US Rebuttal Submission, Attachment II.

¹³ See Vienna Convention on the Law of Treaties, Article 32 ("Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.").

¹⁴ EC Answers of March 7, 2005, para. 22.

question of whether or not this agreement should apply to measures taken for the protection of animal welfare and of the environment, as well as of consumer interests and concerns".

17. The EC then goes on to assert "The bracketed text (which included a reference to the environment) disappeared in the final text of the agreement, as we all know. As a result, environmental damage per se does not fall under the scope of the SPS Agreement." What the EC fails to explain, however, is precisely what that "bracketed text" contained. As a result, and as explained below, the EC's assertions are completely baseless.

18. The "bracketed text" referred to above is actually two different bracketed phrases. Both of these phrases are contained in the concluding paragraph of the Annex A(1) definition of "SPS measure" (that is, in the paragraph following lettered paragraphs *a* to *d*) – a paragraph which (in its final form) describes types of measures – such as labelling and quarantines – as opposed to describing particular types of risks.¹⁵ One of the bracketed phrases would have expressly included animal welfare, environment, and consumer interests and concerns.¹⁶ The second bracketed phrase would have expressly excluded those issues.¹⁷

19. The final text of the SPS Agreement drops both the proposal for an explicit inclusion and the proposal for an explicit exclusion of environmental and animal welfare concerns. Thus, contrary to the EC's assertions, this change is *not the least bit instructive* on whether the drafters of the agreement intended to include or exclude environmental issues. On the other hand, this change could support an interpretation that the drafters decided to leave the last paragraph of Annex A(1) to describe types of measures (such as labelling and quarantines) and to place the types of covered risks within the lettered paragraphs *a* to *d*.

20. Moreover, the EC does not make note of a more relevant and significant change between the late 1990 draft text and the final SPS Agreement. The late 1990 draft text did not include footnote 4, which defines "animal" to include "wild fauna" and "plant" to include "wild flora." The fact that these clarifications were added to the text means that the issue of environmental damage was in fact considered by the drafters, and that the drafters purposely and specifically decided to include damage to wild flora and fauna within the scope of the SPS Agreement. Thus, contrary to the EC's assertions, the negotiating history of the SPS Agreement provides no support for the EC's contention that the SPS Agreement was not intended to cover damage to the environment.¹⁸

¹⁵ That paragraph, in its final form, states "Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

¹⁶ The first bracketed phrase, which followed "packaging and labelling requirements directly related to food safety" in the concluding paragraph to Annex A(1), was "[measures for the protection of animal welfare and of the environment, as well as of consumer interests and concerns]." MTN.GNG/NG5/WGSP/7, Annex A (20 November 1990). This phrase would have explicitly included these issues within the scope of an SPS measure.

¹⁷ The second bracketed phrase was in a new sentence at the end of the concluding paragraph to Annex A(1): "Requirements concerning quality, composition, grading, [consumer preferences, consumer information, animal welfare, the environment or ethical and moral considerations] are not included in the definition of sanitary or phytosanitary measures." MTN.GNG/NG5/WGSP/7, Annex A (20 November 1990).

¹⁸ The EC also asserts that the "negotiating history of the SPS Agreement supports the European Communities view that Annex A.1 must be interpreted strictly and not in a broad manner." EC Answers of

For the European Communities:

135. In paragraph 52 of the EC Responses to the Questions from the Panel (16 June 2004) that "Since the late '80s, the EC institutions are required to provide an explanation of the reasons for not following the opinion of the specific scientific committee relevant to the matter under consideration". Are these explanations made public or provided to the notifier concerned?

21. The United States notes that the EC answer to this question – "yes" – needs more of an elaboration than the EC gave in order not to leave a misimpression. In the context of this dispute, the situation referred to in this question arises when member States continue to oppose approvals of biotech applications after those applications have received positive assessments by EC-level scientific committees. As the EC's product histories show, in many cases member States requested more information without providing any explanations (public or otherwise) for why that member State did not accept the scientific committee's positive assessment.

22. Perhaps the EC's answer was intended to mean that had the EC actually made a final decision on a biotech application during the period October 1998 through August 2003 – instead of imposing a moratorium on final decisions – then the EC institution involved would have had to issue a reasoned decision if that decision departed from the view of the EC scientific committee.

136. In the context of paragraph 195 of the EC Responses to the Questions from the Panel (16 June 2004), does the EC maintain that the appropriate level of protection that might be relevant to a definitive action is different from the ALOP that would be relevant to a provisional measure taken in the face of insufficient scientific evidence?

23. The United States has two comments on the EC's response to this question. First, the EC answer assumes that EC member States and the EC itself have adopted different levels of protection. However, there is no basis in the record for this assertion by the EC. In fact, when the Panel in Question 162 asked the EC to elaborate on any supposed differences in levels of protection, the EC did not provide a specific response, and did not explain how the EC member States might have a different level of protection than that adopted by the EC itself. Instead, the EC asserted only that:

March 7, 2005, para. 20. The United States does not agree that the negotiating history supports any such view. The United States also notes that the EC statement is inconsistent with the EC's own position elsewhere in the same submission, where the EC states that: "In short, the European Communities does not consider that Annex A.1 of the SPS Agreement should be given either a narrow interpretation or a 'broad' interpretation." EC Answers of March 7, 2005, para. 12. The most instructive factor in interpreting Annex A(1) is of course the text itself. In this regard, the United States notes that the text uses *inclusive* language. In particular, footnote 4 is drafted to make clear that the definitions in the footnote are inclusive and not limiting:

"animal" *includes* fish and wild fauna; "plant" *includes* forests and wild flora; "pests" *include* weeds; and "contaminants" *include* pesticide and veterinary drug residues and extraneous matter.

Also, paragraph (d), covering "other damage", is plainly a catch-all provision, and undermines any EC contention that Annex A(1) is to be construed "strictly" or "narrowly."

"It is not possible to describe an 'appropriate level of protection' in general terms. It is clear from the terms of the above measures that they seek to secure a high level of protection."¹⁹

24. Second, the EC seems to be stating that the appropriate level of protection for provisional measures may differ from the level of protection for other (non-provisional) measures. The United States fails to see any basis in logic or in the text of the SPS Agreement for this assertion. Members must select an appropriate level of protection, and then must ensure that any measures adopted to meet that level "are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection."²⁰

For all parties:

140. With reference to (1) Codex standards 192 and 193, (2) IPPC and (3) ISPM 11:

(a) Are they "rules of international law applicable in the relations between the parties to this dispute " within the meaning of Article 31(3) of the Vienna Convention on the Law of Treaties?

(b) May they be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement, as the United States appears to suggest in its rebuttal at para. 6 of attachment II? (The United States is invited to provide elaboration on its statement at para. 6.)

25. Please see the above US comments in relation to Question 119.

141. With reference to Annex (B)(1) of the SPS Agreement, please answer the following questions:

(a) Does the term "sanitary and phytosanitary regulations" cover administrative decisions which relate to the operation of approval procedures and which are generally applicable?

(b) May the phrase "sanitary and phytosanitary regulations which have been adopted" be interpreted to encompass also sanitary and phytosanitary regulations which have been adopted de facto (e.g., generally applicable decisions which have been reached informally and which are unrecorded)?

26. The EC's answer to this question – that a measure like the moratorium on biotech approvals cannot be "adopted de facto" (as the term "de facto" is used in the question) – is completely without merit. The EC's entire argument is based on the EC's unsupported assertion that the word "adopted" connotes some sort of "formal context."²¹ The EC has no basis for this assertion. The normal meanings of the verb "adopt" are to "choose for one's own practice, take up"; or "approve, accept."²² Nothing in the normal usage of the verb "adopt" entails a "formal context." Thus, the EC has presented no reason why a measure like the moratorium – which was adopted and applied to all

¹⁹ EC Answers of March 7, 2005, para. 120.

²⁰ SPS Agreement, para. 5.6.

²¹ EC Answers of March 7, 2005, para. 95.

²² New Shorter Oxford English Dictionary (1993), p. 29.

pending biotech product applications – cannot be "adopted," as that phrase is used in Annex B of the SPS Agreement.

27. The United States also makes note of the EC's statement that "the European Communities can only repeat that it is not possible, in the Community jurisdiction, to adopt an act with legal effects that is 'unrecorded'."²³ This assertion, however, is directly contradicted by the EC's own claim that it adopted an "interim approach." As the EC described it, under that approach the EC would not approve products unless those products met standards of new, yet to be enacted legislation (and changing approval standards is certainly an act with a "legal effect"). Yet, this approach apparently went "unrecorded" – it certainly was never published in the EC's official journal nor notified to the WTO.

144. The Panel notes that a number of products containing the same transgenic modifications as products at issue in this dispute were previously approved by the European Communities prior to July 1998 (eg, swede rape tolerant to glufosinate ammonium (MS1, RF1) and (MS1, RF2); swede rape tolerant to glufosinate ammonium (Topas 19/2); maize tolerant to glufosinate ammonium (T25); maize expressing the Bt cry1A(b) gene (MON 810); maize tolerant to glufosinate ammonium and expressing the Bt cry1A(b) gene (Bt-11); soybean tolerant to glyphosate; chicory tolerant to glufosinate ammonium; maize Roundup Ready NK603). To what extent and how were the previous assessments of potential risks to human, animal or plant health and/or the environment associated with these transgenic modifications taken into consideration in the evaluation of potential risks arising from the products at issue before the Panel?

28. The United States notes that it does not agree with the EC's claim that "as explained in previous EC submissions and confirmed by Dr. Nutti at the hearing, the understanding of the concept of substantial equivalence has greatly evolved since 1998."²⁴ The EC has not established, as it implies, that "substantial equivalence [was] recognised to constitute a risk assessment in itself." Likewise, the United States did not understand Dr. Nutti to be supportive of this claim, nor did the United States understand that Dr. Nutti agreed with the EC's more general claim that "the understanding of the concept of substantial equivalence has greatly evolved since 1998."

154. At paras. 27 and 30 of the European Communities' second oral statement, reference is made to concerns regarding "regulatory requirements outside the scope of this dispute (traceability and labelling)". Is it the European Communities' view that any delays that may have occurred as a result of member States invoking the need for legislation on traceability, labelling or coexistence were justified? Why?

29. The EC's response to this question is illogical, and lacking in any legal or factual basis. The EC's entire response is as follows:

"When referring to 'regulatory requirements outside the scope of this dispute (traceability and labelling)' the European Communities was referring to the fact that the Complainants have not claimed that the requirements relating to traceability and labelling set out in its GMO legislation were unjustified. Accordingly, delays

²³ EC Answers of March 7, 2005, para. 97.

²⁴ EC Answers of March 7, 2005, para. 103.

resulting from the need to satisfy these requirements cannot be considered to be "undue" or contrary to the WTO Agreements."²⁵

30. First, the EC is correct that the United States in this dispute has not taken issue with the specific requirements contained in the traceability and labelling legislation. However, the EC has not explained what the relevance of the particular requirements of such legislation might be to the present dispute. The traceability and labelling legislation did not even enter into force until April 2004 – which is eight months after the terms of reference of this Panel were established. Moreover, the EC has denied that it delayed any final decisions on product approvals until such legislation entered into force.

31. Second, to the extent that the EC is arguing that it would be entitled to adopt a moratorium until traceability and labelling legislation entered into force in April 2004, the United States submits that such a delay would indeed be "undue" under Annex C of the SPS Agreement. As explained in the US answer to Question 173, a Member's supposedly inadequate legislation cannot excuse a member from its SPS obligations, including the obligation under Annex C(1)(A) to undertake and complete approval procedures without "undue delay."

158. In paragraph 313 of the EC Responses to the Questions from the Panel (16 June 2004) the European Communities states that the absence of final consent from the lead CA does not mean that the applicant is not entitled to place the product on the market. Has the product at issue (canola/oilseed rape MS1/RF1 and MS1/RF2) been sold in all of the European Community, including in France, and if not, why not?

32. It is remarkable that the EC asserts that canola/oilseed rape MS1/RF1 and MS1/RF2 have been approved for sale in the EC. As the complainants have explained, the EC deliberate release legislation clearly provides that the lead competent authority must take the final step of placing the product on the market.²⁶ The United States would also note that the Commission's own official status document on biotech approvals shows that France has failed to take the final step of placing the product on the market.²⁷

²⁵ EC Answers of March 7, 2005, para. 110.

²⁶ Directive 90/220, art 13.4 "(Where the Commission has taken a favourable decision, the competent authority shall give consent in writing to the notification so that the product shall be placed on the market . . ."); *Id.* art. 13.5 (Once a product has received a written consent, it may be used without further notification throughout the Community"). Directive 2001/18 includes comparable provisions. 2001/18, art. 18.2 ("Where a favourable decision has been taken, the competent authority which prepared the report shall give consent in writing to the placing on the market . . ."); *Id.* art. 19.1 ("only if a written consent has been given for placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community . . .").

²⁷ Questions and Answers on the Regulation of GMOs in the EU, MEMO/02/160 Rev., Brussels 4 March 2003 (Ex. US-107), at page 14 (MS1/RF1 "not finally approved by F"); page 15 (MS1/RF2 "not finally approved by F").

160. What is the current status of Italy's safeguard measures on maize Bt11, MON 809, MON 810 and T-25? If these products are now permitted to be marketed in Italy, as of when was this marketing permitted?

33. The United States does not understand the EC's contention that this safeguard measure adopted by Italy was repealed in July 2004.²⁸ To the contrary, the United States understands that the safeguard remained in force at least through November 2004, because at that time the measure was subject to a ruling by the Regional Administrative Tribunal.²⁹ The United States further notes that although the Tribunal ordered that the safeguard measure be annulled, the United States has no information indicating that the Government of Italy has actually implemented the tribunal's order by annulling the safeguard.

34. In any event, however, the central fact remains that the Italian safeguard was in force at the time the Panel was established in August 2003. The United States, as explained previously, submits that the Panel should make findings on the EC measures as of August 2003. The DSU contemplates separate proceedings for determining whether a measure found to be inconsistent with a Member's WTO obligations remains in existence or has been made consistent with a covered agreement.

For Argentina, European Communities and the United States:

169. With respect to the safeguard measures invoked for Maize Bt-176, please list the scientific evidence on which the concerns raised by Austria and Germany on potential adverse effects on non-target organisms were based (August 2003).

35. The United States has three comments on the EC's response to Question 169.

36. First, the EC response states that the EC "again summarises" the reasons given by Austria and Germany for adopting these safeguards. The EC's March 7, 2005 answer to question 169, however, is the first time in this dispute that the EC has described in any detail the purported rationales for any of the member State safeguard measures.

37. Second, the EC does not assert that any of the rationales put forth by Austria or Germany are in fact correct,³⁰ nor that such rationales provide the basis for a product ban (as would be required for such a measure under the obligations set out in the SPS Agreement). The reluctance of the EC to make such claims is understandable, in light of the fact that the Commission itself disagrees with the member States' decisions to adopt safeguards. Furthermore, the EC does not dispute that the EC's own scientific committees examined and rejected all of the rationales put forward by the member States. The EC also does not discuss whether, or how, the analysis of the EC's own scientific committees was in any way inadequate.

38. Third, the EC does not address whether the member States sought "to obtain the additional information necessary for a more objective assessment of risk" or "review[ed] the sanitary or

²⁸ The EC's supporting exhibit (EC-166) contains a copy of a letter from the Government of Italy to the Commission, but the exhibit does not include an official document from the Italian health ministry repealing the safeguard measure.

²⁹ The ruling, which appears to be included in the Ex. EC-166, resulted from a legal proceeding brought by seed companies and a biotech association.

³⁰ To the contrary, the EC's language – by using phrases such as "Austria and Germany consider" and "According to Austria and Germany," – is carefully qualified so as not to indicate whether the EC even agrees with the rationales put forth by the member States.

phytosanitary measure accordingly within a reasonable period of time," as required under Article 5.7. Nor does the EC discuss whether there may have been less trade-restrictive measures (such as measures other than complete product bans) that would have met the concerns expressed by the member States. For example, the member State concerns are addressed to purported risks associated with planting, but the safeguards ban all uses of the biotech products, including import and processing.

39. Thus, although the EC for the first time has described purported rationales for certain member State safeguards, the EC has not begun to develop the information and arguments that would be needed for the Panel to consider a claim that these safeguards met all the requirements of Article 5.7. Rather, the most pertinent information on the record remains that the EC's own scientific committees found that the available evidence was sufficient for the completion of risk assessments, that those committees made positive assessments, and those committees reviewed and rejected the rationales put forth by the member States in relation to the safeguard measures.

For all parties:

170. With reference to EC Directive 2001/18, Annex II, Section C.2.1, please indicate for each of the listed potential adverse effects of GMOs whether measures applied to prevent or minimise such effects fall within the scope of Annex A(1) of the SPS Agreement, and if so, why. The parties are also invited to address Section D with the same question in mind.

40. Please see the above US comments in relation to Question 119.

For Argentina, the United States and the European Communities:

176. With reference to Austria's safeguard measure on Bt-176 maize, please comment on the reference in exhibit EC-158 att. 7 to insufficient labelling requirements laid down in the Commission Decision relating to the relevant product. In particular, what is the basis for the concern expressed about insufficient labelling (e.g., food safety, consumer information, etc.), and how does the labelling issue affect the analysis of whether the Austrian safeguard measure falls within the scope of the SPS Agreement and/or the TBT Agreement?

41. The EC response on Austria's purpose for requiring food labelling is not supported by the exhibits. The EC reasoning is as follows:

"The second concern (the insufficient labelling for the purpose of effective and fair consumer information) is also an issue that is independent and not related to any component of the risk analysis process to tackle any of the risks to human, animal or plant life or health, which may be at stake in the Austrian provisional measure."

"Indeed, the Commission Decision for this product states (fifth recital, 6th indent) that 'there are no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques'.³¹

42. To be sure, the Commission found that there were no food safety grounds for labelling the product. But the question posed by the Panel is why Austria wanted additional labelling. And Austria, of course, disagreed with the Commission on many issues – that is why it adopted the safeguard. And, as the United States noted in its prior answer to this question, the Austrian

³¹ EC Answers of March 11, 2005.

memorandum does indicate an Austrian concern with purported risks to human health from antibiotic resistance marker genes. Thus, the EC has no basis for asserting that Austria's concerns regarding labelling were unrelated to purported risks to human health.

200. With reference to para. 20 of the European Communities' second oral statement (concerning Bt cotton 531), is the European Communities asserting that the applicant was formally required or requested to submit the information in question? If so, please provide support.

43. The issue with Bt cotton 531 is that the Regulatory Committee voted on the application in February 1999 and failed to reach a qualified majority to approve or disapprove; that the EC did not follow its own procedures by then sending the application on to the Council and if necessary, the Commission, for final decision; and that the application then languished for over 3 years, without any activity other than purported "*interservice consultations*," until the application was updated in early 2003 to meet the requirements of Directive 2001/18.³² This delay, as the United States has explained, is a clear example of the EC applying its moratorium to a product that under EC law, should have proceeded promptly to a final decision.

44. At the second substantive meeting, the EC tried to justify this lengthy delay by claiming that in fact there were outstanding requests for information that justified the delay of more than 3 years, and that those requests for information were reflected in the comments of the member States during the vote of the Regulatory Committee.

45. In its response to Question 200, the EC now retreats from this assertion. In particular, the EC claims that in its oral statement, it only meant to make the point that member State objections before "February 1999" – that is, prior to the Regulatory Committee vote – were transmitted to the applicant. The United States appreciates that the EC is no longer contending that a non-decision in the Regulatory Committee is equivalent to a request for information. In fact, elsewhere in its answers, the EC states that the Regulatory Committee voting procedure cannot serve as a request for information:

"The role of a Regulatory Committee is to vote on a proposal for a decision presented by the Commission. It cannot itself propose any decision nor amend the one proposed by the Commission. Equally, it does not itself have any power to seek further information from the applicant. If the Regulatory Committee does not endorse the Commission's proposal, the procedure moves up to the next level."³³

Having dropped its argument that the Regulatory Committee vote served as a request for additional information, the EC simply has no rationale for claiming that the delay of more than three years in the consideration of Bt cotton 531 was justified. The only explanation for this delay is that it reflected the EC's decision to adopt a moratorium on making final decisions on biotech product applications.

³² See EC Exhibit 65, Chronology. As the United States explained in its Supplementary Rebuttal (paras. 40-51), the applicant took the initiative to provide some updated information in 2002, although this information was not requested by the EC.

³³ EC Answers of March 7, 2005, para. 124 (emphasis added).

ANNEX F-4

REPLIES BY CANADA TO QUESTIONS POSED BY THE PANEL
IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
7 MARCH 2005

For all parties:

119. With reference to exhibit US-123 (reproduced at para. 9 of attachment II of the US rebuttal), do the references in ISPM 11 to "indirectly affect plants [...] by other processes such as competition" (page 34) and "significant reduction, displacement, or elimination of other plant species" (page 19) support the view that the term "injurious" in the IPPC definition of "pest" ("any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products") should be given a broad interpretation?

1. Yes. The references in ISPM No. 11 support the view that the term "injurious" in the IPPC definition of "pest" should be given a broad interpretation. In turn, the broad interpretation given to the term "pest" in ISPM No. 11 confirms that the ordinary meaning of the term "pest" in the *SPS Agreement*, in its context and in the light of the object and purpose of the *SPS Agreement*, should be given a broad interpretation. Such a broad interpretation is consistent with the definition of "pest" in the *SPS Agreement* which has been defined to include "weeds". The references in ISPM No. 11 cited in the Panel's Question are examples of the type of injury to plant life and health that can be caused by weeds or other invasive plant pests.

2. That being said, for something to qualify as a "pest" for the purposes of ISPM No. 11 it must be "injurious" to plants or plant products in the sense of causing damage, either directly or indirectly, to plant life or health. Similarly, in the light of the object and purpose of the *SPS Agreement*, for something to be considered a "pest" for the purposes of the *SPS Agreement*, it must be "injurious" to plants, animals, or humans in the sense of causing damage, either directly or indirectly, to life or health. The presence of a biotech seed or crop would not be "injurious" to plants or plant products merely because that presence caused an economic loss resulting from a legal restriction imposed on the marketing of a product. Such an economic loss is a consequence of the decision to impose arbitrary thresholds for the admixture of transgenic and non-transgenic products – a decision relating to the marketing of a product, rather than to protect plant life or health.

3. Canada wishes to anticipate Question 140 of the Panel regarding the relevance of the IPPC and ISPM No. 11 to the interpretation of the term "pest" in the *SPS Agreement*. Canada notes that the 1997 revised text of the IPPC ("IPPC 1997"), which contains the definition of "pest" cited above in Question 119, is not yet in force, as the requisite two-thirds of the contracting parties to the IPPC have not yet deposited their instruments of acceptance of the amendments to the IPPC, as reflected in IPPC 1997.¹ Consequently, the IPPC 1997 cannot be considered to be a "rule[] of international law" under Article 31(3)(c) of the *Vienna Convention on the Law of Treaties*. If the IPPC is to be considered a "rule[] of international law", it is the 1979 version that must be so considered.²

¹ See Article XIII of the IPPC 1979. Also see Canada's Answers to Questions from the Panel (16 June 2004), Question 4.

² The IPPC 1979 defines "pest" as "any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant products;".

4. That being said, ISPM No. 11 incorporates the updated definition of "pest" used in the IPPC 1997.³ As Canada explains in its response to Question 140, ISPM No. 11 may be considered as a supplementary means of interpretation for terms in the *SPS Agreement* pursuant to Article 32 of the *Vienna Convention*. Although the IPPC 1997 is not yet in force, it nonetheless would be consistent with the object and purpose of the *SPS Agreement* to consider the updated version of the definition of "pest" as a supplementary means of interpretation given that the ISPM No. 11 has been endorsed by the Interim Commission on Phytosanitary Measures as an international phytosanitary standard.

120. With reference to Annex A(1)(d) of the SPS Agreement, please answer the following questions:

- (a) What is the meaning of the term "other damage"?**
- (b) Does the term "other" imply that Annex A(1)(a) through (c) are also about "damage"? If so, does the term "other damage" cover damage sustained by plants, animals or humans other than damage to their "life or health"? Please provide examples.**
- (c) Is "other damage" limited to damage sustained by plants, animals or humans? If not, please provide examples.**

5. As the answers to the three above questions tend to overlap, Canada will group its answers to these questions together.

6. The ordinary meaning of the term "damage" is "harm done to a thing...; *esp.* physical injury impairing value or usefulness."⁴ The context of the term "damage" includes the definitions set out in Annex A of the *SPS Agreement*, in particular the definition of "risk assessment", and other provisions of the *Agreement*, in particular Article 5.3. The definition of "risk assessment" requires an evaluation of both the likelihood of an event occurring (*e.g.* the entry, establishment or spread of a pest) as well as the "associated potential biological and economic consequences". Article 5.3 requires WTO Members to take into account, in assessing the risk to animal or plant life or health, "the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication...and the relative cost-effectiveness of alternative approaches to limiting risks."

7. Thus, the context suggests that "damage" means the injurious or harmful potential biological and economic consequences that result from the occurrence of an event. The concept of "damage" in the *SPS Agreement* is subsumed within the concept of "risk". "Risk" refers to the likelihood of an event occurring as well as the extent of potential damage associated with that event.⁵

8. The term "other" implies that Annex A(1)(a) and (c) are also about "damage". However, while Annex A(1)(a) and (c) involve an evaluation of the likelihood of the event occurring (*e.g.* entry, establishment and spread of pests or diseases) as well as any associated damage to life or health, Annex A(1)(d) is only concerned with the "other damage" that flows from the entry, establishment or

³ ISPM No. 11, "Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms", April 2004, p. 6. (Exhibit EC-130)

⁴ *The New Shorter Oxford English Dictionary*, vol. 1 (Oxford: Clarendon Press, 1993), p. 588. (Exhibit CDA-202)

⁵ See *Australia – Salmon*, Report of the Panel, para. 8.72 and 8.116, where the Panel considered the two types of risks to be evaluated in a risk assessment: (i) the risk of entry, establishment or spread and (ii) the risk of the associated potential biological and economic consequences.

spread of pests. Annex A(1)(d) presupposes that damage to animal or plant life or health from the entry, establishment or spread of pests has been established. Consequently, Annex A(1)(d) is concerned only with "other damage."

9. The use of the term "other" in Annex A(1)(d) suggests that the type of damage contemplated in Annex A(1)(d) is distinct from the damage to animal or plant life or health (Annex A(1)(a)) and human life or health (Annex A(1)(c)) arising from the entry, establishment and spread of pests. Canada recalls that the terms "animal" and "plant" are defined broadly in the *SPS Agreement*.⁶ Accordingly, many of the risks to biodiversity or the environment cited by the EC falls within the risks to animal and plant life or health contemplated by Annex A(1)(a).⁷ In terms of the second question in Question 120(b), Canada does not consider that plants, animals, or humans can be "damaged" unless there is damage to their "life or health". In the light of Canada's response to Question 119, it would be inconsistent with the object and purpose of the *SPS Agreement* to extend the definition of damage to plants, animals or humans to include so-called damage that is not based on injury or harm to their life or health. In this particular context, reduced yield of a crop, as a result of competition from a pest such as a weed, would be considered impairment to the health of the crop plant.

10. In terms of Question 120(c), "other damage" is not limited to damage sustained by plants, animals or humans. "Other damage" includes damage from the entry, establishment or spread of pests to the functioning of the environment or the ecosystem taken as a whole, independent of damage to the life or health of specific plants or animals. This would include, for example, damage resulting from ecosystem destabilization and from control, eradication or management programs that would be needed if a quarantine pest was introduced, and impacts of such programs (e.g. pesticides...) on biological diversity. Canada refers the Panel to paragraphs 64-65 of Canada's Third Written Submission, which discusses the Interim Commission on Phytosanitary Measures' *Guidelines On The Understanding of Potential Economic Importance and Related Terms Including Reference To Environmental Considerations*.⁸

11. Specific examples of "other damage" may include:

- environmental and other undesired effects of control measures;
- capacity to act as a vector for other pests;
- significant effects on designated environmentally sensitive or protected areas;
- significant changes in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling etc.);
- effects on human use (water quality, recreational uses, tourism, animal grazing, hunting, fishing); and
- costs of environmental restoration.⁹

⁶ *SPS Agreement*, Annex A, footnote 4.

⁷ Canada Third Written Submission, paras. 55 to 65.

⁸ Exhibit CDA-151, pp. 2-3.

⁹ ISPM No. 11, "Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms", April 2004, pp. 23-24. (Exhibit EC-130)

121. With reference to Article 5.1 of the SPS Agreement, what were the relevant risk assessment techniques developed by the relevant international organizations that the European Communities had to take into account in the relevant period (October 1998 – August 2003)?

12. During the period in question (October 1998 – August 2003), there were no "relevant risk assessment techniques" that had been developed by "relevant international organizations". While risk assessment guidelines were in the process of being developed in "relevant international organizations" such as the Codex Alimentarius Commission (Codex) and under the auspices of the International Plant Protection Convention (IPPC), during the relevant period, these guidelines remained in the draft stages.

13. Even if we assumed, for the sake of argument, that Annex III of the *Cartagena Protocol on Biosafety* (BSP) constituted a "relevant risk assessment technique" and that it had been developed by a "relevant international organization" – and Canada does not agree with either of these two propositions – the BSP was not in force during the relevant period of time. It only came into force on September 11, 2003.

122. Please explain your views as to the relationship between a Member's appropriate level of protection and the requirement in Article 5.1 to ensure a measure is based on a risk assessment, as appropriate to the circumstances. Is the appropriate level of protection relevant to the conduct of the risk assessment?

14. The appropriate level of protection (ALOP) is not directly relevant to the conduct of the risk assessment. It is, however, relevant once the risk assessment has been completed and, assuming that a risk has been identified, a risk management measure has to be selected.

15. This is reflected in the international standards for risk assessment that have been developed, for example, in Codex and under the auspices of the IPPC. A review of the *Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*¹⁰ (Codex Principles) reveals that the ALOP is not a relevant consideration in conducting either the safety assessment or the risk assessment. For instance, under Section 3 – Principles, paragraph 10 states that:

Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity...If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.¹¹

16. It is noteworthy that in the quoted statement, which sets out the basic principle with respect to the conduct of a risk assessment under the Codex Principles, there is no indication that the level of protection chosen by the country conducting the risk assessment is a factor to be taken into account.

17. Similarly, ISPM No. 11 makes no mention of the ALOP as a factor or determinant in the conduct of a pest risk assessment. It is at Stage 3 – Pest Risk Management – that ISPM No. 11 addresses the role of acceptable levels of risk.¹²

¹⁰ Exhibit EC-44.

¹¹ *Ibid.*, p. 44.

¹² ISPM No. 11, "Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms", April 2004, p. 28. (Exhibit EC-130)

18. In short, neither the Codex Principles, nor ISPM No. 11, support an argument that the conduct of the risk assessment is affected in any way by the ALOP. To the contrary, they confirm that the conduct of a risk assessment relies on the best and most complete scientific information available in order to enable the risk assessor to identify the hazards and characterize the risks with as much certainty as is possible.

19. Put differently, a risk assessment is conducted according to pre-established parameters. These parameters reflect the range of hazards that could arise from the activity or product in question. According to present international standards, the risk assessor should have the best available information at his or her disposal in order to assess the hazards and characterize the potential risks with as much certainty as is possible. The value of the risk assessment hinges on the degree of certainty with which the risk assessor can state his or her conclusions. This is true regardless of the ALOP sought to be achieved.

20. The risk manager, in turn, weighs the conclusions of the risk assessment in light of the ALOP and, on that basis, selects the risk management measure that is expected to achieve that level of protection.

21. It is true that the first part of the definition of risk assessment in paragraph 4 of Annex A refers to "the evaluation of the likelihood...according to the sanitary or phytosanitary measures which might be applied", but this language does not imply that the conduct of the risk assessment is influenced by the *level* of protection sought to be achieved. It simply requires the WTO Members to examine the range of risk management measures available in light of the risks that have been identified. The chosen level of protection may influence the range of risk management measures available, but it does not affect the identification of hazards and the characterization of any consequent risks.

22. In short, whether the chosen level of protection is low or high does not affect the risk assessor's need to have sufficient information at his or her disposal to come to a conclusion that is as certain as possible. A risk assessment that is characterized by significant uncertainty as to the likelihood or magnitude of adverse effects occurring is less helpful to the risk manager, regardless of the level of protection sought to be achieved because it is less likely to serve as an accurate predictor with respect to whether that level of protection will actually be achieved.

123. Please assume for the sake of argument that Article 5.7 of the SPS Agreement provides for an exception in the nature of an affirmative defence:

(a) Could the Panel assess the merits of any such defence without having previously found an inconsistency with Article 2.2 of the SPS Agreement?

23. Technically, the Panel could assess a measure against Article 5.7 without first making a determination whether that measure was inconsistent with Article 2.2. However, the first question that would have to be answered is whether there was insufficient evidence to complete a risk assessment. It is only if there is insufficient evidence to complete a risk assessment that Article 5.7 is available as a defence. The insufficiency of the evidence means that the measure cannot be based on a risk assessment, and that it is being maintained without sufficient scientific evidence. In other words, the measure is *ipso facto* inconsistent with Articles 5.1 and 2.2, at least on a provisional basis. Conversely, if there is sufficient scientific evidence to complete a risk assessment, the measure cannot benefit from the protection afforded by Article 5.7, and the analysis has to revert to the question of whether the measure is in fact based on a risk assessment and therefore maintained with sufficient scientific evidence.

24. Hence, in a practical sense, the need to assess the merits of a defence under Article 5.7 should not logically arise unless the defending party concedes that its measure does not meet the requirements of Article 2.2. That is, the defending party would have to assert that its measure was being maintained without sufficient scientific evidence because sufficient scientific evidence did not exist to complete a risk assessment. Having invoked Article 5.7, it would then be for the defending party to establish a *prima facie* case that the circumstances were such that the "relevant scientific evidence is insufficient" to complete a risk assessment, and that the measure meets all of the requirements of Article 5.7.

25. Thus, an inconsistency with the requirements of Article 2.2 – whether conceded by the defending party or determined by the Panel through its own analysis – is a natural precursor to turning to Article 5.7 to see if the measure cannot be justified on other grounds.

26. That this is correct seems clear from the approaches taken by the panels in *Japan – Agricultural Products II* and *Japan – Apples*. In both cases, the complaining party alleged a violation of Article 2.2. In neither case did the complaining party assert a violation of Article 5.7 as part of its claim. The defending party raised Article 5.7 as an alternative defence, predicated on a finding by the panel that the measure was being maintained without sufficient scientific evidence. The panels in those two cases came to the conclusion, on a provisional basis, that the measure in question was being maintained without sufficient scientific evidence.¹³ The panel in each case then noted that Japan had invoked Article 5.7 as an alternative defence. That is, the panels concluded that if the measure met the requirements of Article 5.7, then they could not conclude that Article 2.2 had been violated. Both panels went on to conclude that the measures in question did not meet the requirements of Article 5.7, and, on that basis, the panel in each case confirmed the violation of Article 2.2.

27. In other words, in both cases, the question of whether Article 5.7 applied was meaningful or relevant only because the panels had first determined that the measure in question was being maintained without sufficient scientific evidence.

(b) If not, in a case such as this one where a claim of inconsistency with Article 2.2 of the SPS Agreement is based on a claim of inconsistency with Article 5.1 of the SPS Agreement, would it be correct for the Panel to begin its analysis with the Article 5.1 claim, then move to the consequential Article 2.2 claim and finally turn to the Article 5.7 defence?

28. Yes. Given the jurisprudence,¹⁴ it seems axiomatic that a measure that is not based on a risk assessment is necessarily inconsistent with Article 2.2, third element (likely also second element). Therefore, determining whether the measure is not based on a risk assessment, that is, whether Article 5.1 has been violated, logically precedes a determination whether Article 2.2 has been violated. Once a provisional finding has been made that the measure is being maintained without sufficient scientific evidence, contrary to Article 2.2, it is for the defending party, if it so chooses to invoke Article 5.7 as a defence on the initial grounds that insufficient evidence exists to complete a risk assessment. Thus, the question of whether the measure meets the requirements of Article 5.7 arises, with the burden of proof falling on the defending party as the party who "asserts the affirmative of a particular claim or defence".¹⁵

¹³ *Japan – Agricultural Products II*, Report of the Panel, para. 8.43; *Japan – Apples*, Report of the Panel, para. 8.199.

¹⁴ *Australia – Salmon*, Report of the Appellate Body, para. 138.

¹⁵ *US – Wool Shirts and Blouses*, Report of the Appellate Body, p. 14.

For all complaining parties:

124. With reference to para. 19 of the European Communities supplementary rebuttal, do the complaining parties agree that the Panel "is not asked to determine whether a prudent government, in the abstract, *should* have behaved or not in a certain manner thus causing delay. It merely needs to find whether, in the concrete case and in light of the factual information and the legal arguments before the relevant authorities, that behaviour which in the end caused a delay *could* justifiably have been adopted"?

29. As it has already indicated in its Second Oral Statement, Canada does not agree with the EC's view of the standard of review with respect to paragraph 1(a) of Annex C of the *SPS Agreement*.¹⁶ Canada specifically disagrees with the EC's assertion in paragraph 19 of its Supplementary Rebuttal. In particular, the distinction that the EC seeks to create between the so-called "more general wording" of paragraph 1(a) of Annex C and the, presumably, more specific wording of Article 5.2, is a false and ultimately irrelevant dichotomy.

30. Thus, in Canada's view, the standard of review with respect to whether the EC's measures amount to undue delay under paragraph 1(a) of Annex C is not a question of whether the EC's "behaviour...*could* justifiably have been adopted; it is a question of whether a reasonably diligent government would and should have acted in view of the factual information at its disposal. This characterization is consistent with the Appellate Body's statement in *EC – Hormones* that "the applicable standard is neither de novo review as such, nor 'total deference', but rather the 'objective assessment of the facts'".¹⁷

31. Furthermore, a determination as to whether a WTO Member has violated the obligation in paragraph 1(a) of Annex C to undertake and complete approval procedures "without undue delay" is a question of mixed law and fact. As such, there is no reason for the Panel to adopt a deferential approach to its determination as to what constitutes "undue delay". As the Appellate Body noted in *EC – Hormones*:

In so far as legal questions are concerned – that is, consistency or inconsistency of a Member's measure with the provisions of the applicable agreement – a standard not found in the text of the SPS Agreement itself cannot absolve a panel (or the Appellate Body) from the duty to apply the customary rules of interpretation of public international law.¹⁸

32. In any event, the EC's proposed "standard of review" in paragraph 19 of its Supplementary Rebuttal sounds eerily similar to the standard of review that the EC proposed in *EC – Hormones*. In that case, the EC pointed to Article 17.6(i) of the *Anti-Dumping Agreement* as the basis for what it called a "deferential reasonableness standard" to be applied to factual issues in the *SPS Agreement*. Article 17.6(i) states, in part, that:

In its assessment of the facts of the matter, the panel shall determine whether the authorities' establishment of the facts was proper and whether their evaluation of those facts was unbiased and objective. If the establishment of the facts was proper and the evaluation was unbiased and objective, even though the panel might have reached a different conclusion, the evaluation shall not be overturned.

¹⁶ Canada Second Oral Statement, paras. 97-100.

¹⁷ *EC – Hormones*, Report of the Appellate Body, para. 117.

¹⁸ Report of the Appellate Body, para. 118.

33. The EC argued in that case that this standard is applicable in "all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants".¹⁹

34. A review of the EC's argument in paragraph 19, including its assertion that "the Panel merely needs to look at the applications to satisfy itself that such delays that may have occurred were based on *reasonable justification*",²⁰ and its contention that the panel merely needs to determine whether the "behaviour which in the end caused a delay *could* justifiably have been adopted",²¹ calls to mind the language in Article 17.6(i).

35. The Appellate Body soundly rejected the EC's proposed "deferential reasonableness standard" in *EC – Hormones*.²² This Panel should reject any effort by the EC to resurrect that standard in this dispute.

125. The European Communities' opening statement at the Panel's meeting with the experts includes the following statements:

- "[T]he European Communities' approach is to seek more evidence to establish whether or not there is a risk [...] in order to make a definitive decision on the basis of full information – even if that takes a little more time". (para. 19)
- "The European Communities reacts [to uncertainty as to the appropriate risk management strategies] by saying 'let's take our time and reduce the uncertainty'". (para. 17)

Do the complaining parties consider that it would be consistent with Annex C(1)(a) of the SPS Agreement to delay making a definitive decision based on the approach outlined by the European Communities? In answering this question, please take into account the provisions of Article 2.2 of the SPS Agreement²³ and Article 5.7 of the SPS Agreement (adoption of provisional measures based on available pertinent information).

36. Canada refers the Panel to paragraphs 148-150 of Canada's Third Written Submission.

37. Canada agrees that, while there may be circumstances in which the application of a precautionary approach in the selection of the risk management measure is warranted, this must be qualified so as to ensure that the purported application of the precautionary approach does not become a disguise for protectionism. As the Appellate Body found in *EC – Hormones*, while the precautionary approach finds reflection in several of the provisions of the *SPS Agreement*, the precautionary approach does not override the provisions of Articles 5.1 and Article 5.2.²⁴ Similarly, in Canada's view, the precautionary approach cannot override the requirements of Annex C or Article 2.2.

¹⁹ Quoted in *EC – Hormones*, Report of the Appellate Body, para. 113.

²⁰ EC Supplementary Rebuttal, para. 19. (Emphasis added)

²¹ *Ibid.* (Emphasis in the original)

²² *EC – Hormones*, Report of the Appellate Body, para. 114 and 119.

²³ (This footnote appeared in the Panel's question) In *EC – Hormones*, the Appellate Body stated in relation to Article 2.2 that "a panel charged with determining [...] whether 'sufficient evidence' exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned" (para. 124).

²⁴ *EC – Hormones*, Report of the Appellate Body, paras. 124-125.

38. As Canada set out in its Second Oral Statement, in determining whether a Member has complied with its obligations under the *SPS Agreement*, the question is not whether scientific uncertainty exists, but whether there is sufficient scientific evidence to enable the completion of a risk assessment.²⁵ By raising the spectre of "uncertainty" and a lack of "full information", the EC is suggesting that insufficiency of scientific evidence justifies a prolonged delay in the completion of an approval procedure. This is nothing other than an indirect attempt to justify the *product-specific marketing bans* under Article 5.7.

39. Where pre-marketing approval is required for a product to be marketed, the decision by a regulatory authority not to complete the approval procedure on the basis of insufficiency of relevant scientific evidence amounts to a ban on the product.²⁶ Whether or not this ban is adopted in the form of a legal instrument does not affect the application of Article 5.7 to the approval procedure. Thus, a ban arising from a decision not to complete the approval procedure will be exempted from the requirements of Article 2.2, third element, only if the Member is able to demonstrate that the ban satisfies the requirements of Article 5.7. Similarly, in order to justify the delay in completing the approval procedures under Annex C of the *SPS Agreement*, the defending WTO Member would have to demonstrate that the ban satisfies the requirements of Article 5.7. If the ban does not satisfy those requirements, then the delay in completing the approval procedures is "undue".

40. However, despite asserting scientific uncertainty, the EC has not claimed the protection of Article 5.7, let alone demonstrated that its requirements have been satisfied. Instead, the EC appears to assume that Article 5.7 does not apply to the operation of inspection, control and approval procedures. As Canada has previously argued,²⁷ this assumption is invalid. It is incumbent on the EC to demonstrate that the requirements of Article 5.7 have been met where it argues that a risk assessment cannot be completed on the basis of insufficiency of scientific evidence.

126. In paragraph 10 of the EC Responses to the Questions from the Panel (16 June 2004), the European Communities compares the definitions of risk assessment as used in the SPS Agreement and as used in Codex, and concludes that "It is clear that the SPS definition of risk assessment is equivalent to 'weighing policy alternatives in the light of the results of risk assessment' which is part of the Codex Definition to "risk management". Do you agree with this conclusion? Please explain your response.

41. Canada does not agree. Canada refers the Panel to paragraphs 80-95 of Canada's Second Written Submission and paragraphs 15-20 of Canada's Third Written Submission where Canada has responded in detail to the EC's assertions in this regard. Canada's arguments can be summarized as follows.

42. First, to the extent that a risk arises from the entry, establishment or spread of a pest or disease, the risk assessment must evaluate the likelihood of entry, establishment or spread of a pest or disease according to the sanitary and phytosanitary measure which might be applied. Building on the framework adopted by the Appellate Body in *Australia – Salmon*, such a risk assessment must evaluate both (1) the likelihood of entry, establishment or spread and the associated potential biological and economic consequences and (2) evaluate such likelihood according to the SPS measures which might be applied. It is not sufficient to merely identify and evaluate the risks and biological and economic consequences. The reference to "according to the SPS measures which might be applied" implies that different risk management measures or, to use the EC's language,

²⁵ Canada Second Oral Statement, para. 32.

²⁶ Canada First Written Submission, paras. 159 and 255.

²⁷ Canada Third Written Submission, para. 149.

"policy alternatives", that might be applied to control the identified risks – what the Panel in *Australia – Salmon* referred to as "risk reduction factors"²⁸ – must also be evaluated in order for the risk assessment to meet the requirements of the first definition in paragraph 4 of Annex A of the *SPS Agreement*. The reference in Article 5.3 to "the relative cost-effectiveness of alternative approaches to limiting risks" as a relevant economic factor to be taken into account in conducting a risk assessment supports this conclusion.

43. Second, it is important to note that the "policy alternative" that is selected becomes the SPS measure. Pursuant to Article 5.1, the SPS measure in question must be based on the risk assessment, that is, there must be a rational connection between the so-called "policy alternative" and the evaluation of the risks.

44. Third, the EC stresses the distinction between risk assessment *strictu sensu* and risk management and the respective roles of the scientific committees and Regulatory Committee.²⁹ The EC divides the term "risk assessment" into three components: "(1) risk assessment in the narrow sense, i.e. as a 'scientifically based process', and (2) risk management, and (3) risk communication."³⁰ The EC stresses that risk management decisions are made by the Regulatory Committees and risk assessment *strictu sensu* falls to the scientific committees. In other words, the scientific committees are responsible for evaluating the risks while the Regulatory Committees are responsible for selecting the appropriate SPS measure.³¹

45. To the extent that the EC suggests that only the "risk assessment in the narrow sense" must be a "scientifically based process", Canada disagrees. This is tantamount to claiming that only part of the "risk assessment" in the *SPS Agreement* must be science-based, an assertion at odds with the definition of "risk assessment" in Annex A and the requirement to base an SPS measure on a risk assessment.

46. If one accepts, for the sake of argument, that the Regulatory Committees are responsible for "weighing policy alternatives", it follows logically that the Regulatory Committees must have evaluated the various risk management options that might be applied in the light of the risks that were identified in the risk assessment as is required by the *SPS Agreement*. Ironically, the EC quotes in its Responses to Questions from the Panel (16 June 2004) from a decision of the European Court to the effect that if the Regulatory Committee disregards the scientific opinion, "it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question."³²

²⁸ *Australia – Salmon*, Report of the Panel, paras. 8.89 and 8.90. The Appellate Body endorsed this approach in para. 134 in concluding that Australia failed to fulfil the third requirement of the first definition of risk assessment, namely "the required evaluation of the likelihood of entry, establishment or spread of the diseases of concern according to the SPS measures which might be applied."

²⁹ See generally EC Responses to Questions from the Panel following the First Substantive Meeting (16 June 2004), Question 2, para. 12 and EC Second Written Submission, paras. 27-31.

³⁰ EC Second Written Submission, para. 21. [emphasis added]

³¹ It should be noted that the EC has consistently de-emphasized the role of the Commission. The Commission is responsible for drafting the measure to be placed before the Regulatory Committee after inter-service consultation; if the Regulatory Committee fails to act, the Commission is obligated to refer the draft measure to Council without delay; if Council fails to act within three months, the Commission is obligated to adopt the measure.

³² EC Responses to Questions from the Panel following the First Substantive Meeting (16 June 2004), Question 17, para. 57.

47. In not one instance has the EC itself put forth information of this nature that would justify ignoring the advice of its own scientific committee. In the more than six years since the *moratorium* was imposed, the EC has failed to evaluate the SPS measures that might be applied. In a sense, this is not surprising given that with the possible exception of a few cases, the risk assessments have not identified any risks of a different nature or magnitude than those arising from conventional counterparts of the biotech products in question.

127. At para. 42 of Canada's supplementary rebuttal, Canada suggests that crop husbandry includes breeding and that if a scientist employs selective breeding methods in the laboratory, this should qualify as crop husbandry because the scientist would be performing the same operations as a farmer who employs selective breeding methods on the farm. But is the insertion of a transgene part of the breeding of biotech crops? Or is the breeding rather the re-production of the biotech seed?

48. The insertion of a transgene is part of the breeding of biotech crops. As Dr. Andow has stated "breeding involves two important processes: (1) finding and introducing usable genetic variation into the breeding population and (2) improving and selecting desired varieties from the breeding population."³³ Dr. Andow indicated that transgenesis, as well as mutagenesis, is a process to introduce genetic variation into the breeding population. He indicated that transgenesis is "a part of the breeding process", although only one part. Once the transgene has been inserted, the transgenes are introgressed into an elite, adopted germplasm.

49. Dr. Andow's description of modern plant breeding is supported by scientific reports before the Panel. For instance, in Exhibit CDA-195, the authors refer to "breeding" as encompassing conventional breeding techniques as well as breeding using rDNA technology.

50. Thus, in the light of modern plant breeding techniques, it would be artificial to exclude one method for introducing genetic variation – transgenesis – from the concept of "breeding" and crop husbandry.

Questions not Previously Provided to the Parties

For all parties:

140. With reference to (1) Codex standards 192 and 193, (2) IPPC and (3) ISPM 11:

- (a) Are they "rules of international law applicable in the relations between the parties [to this dispute]" within the meaning of Article 31(3) of the Vienna Convention on the Law of Treaties?**

51. Canada does not consider Codex Standards 192 and 193, or ISPM No. 11 to be "rules of international law". Hence they do not fall within the scope of Article 31(3)(c) of the *Vienna Convention*. With respect to the IPPC, Canada refers the Panel to Canada's response to Question 119.

52. Canada also questions the Panel's apparent assumption that the reference to "parties" in Article 31(3)(c) is a reference to the parties in a given dispute. Canada is of the view that the reference to "parties" is a reference to the parties to the treaty that is being interpreted. In the case of the WTO Agreement, the rules of international law in question would have to be applicable in the relations among all the WTO members.

³³ Dr. Andow, Responses to Questions, para. 102.01.

- (b) **May they be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement, as the United States appears to suggest in its rebuttal at para. 6 of attachment II? (The United States is invited to provide elaboration on its statement at para. 6.)**

53. Notwithstanding the fact that Codex Standards 192 and 193, and ISPM No. 11 are not captured by any of the categories of Article 31 of the *Vienna Convention*, they may be relevant as supplementary means of interpretation pursuant to Article 32 in order to confirm the meaning of terms resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31 leaves the meaning ambiguous or obscure, or leads to a result which is manifestly absurd or unreasonable (*e.g.*, the EC's argument that risks arising from allergens in the context of food safety is excluded from the scope of the *SPS Agreement* because the specific term "allergen" is not explicitly included in paragraph 1(b) of Annex A).

141. With reference to Annex (B)(1) of the SPS Agreement, please answer the following questions:

- (a) **Does the term "sanitary and phytosanitary regulations" cover administrative decisions which relate to the operation of approval procedures and which are generally applicable?**

54. Yes.³⁴ The definition found in footnote 5 indicates that the list ("laws, decrees or ordinances") is illustrative rather than exhaustive. Article 7 states clearly that "Members shall notify changes in their sanitary or phytosanitary measures"; this obligation is elaborated upon in paragraph 1 of Annex B, where it states "Members shall ensure that all sanitary and phytosanitary regulations which have been adopted are published promptly...". This would include "administrative decisions which relate to the operation of approval procedures and which are generally applicable". As Canada has already demonstrated, the *moratorium* is a measure that falls within the scope of Article 7 and paragraph 1 of Annex B; therefore the EC was under an obligation to "notify" the "change" in its existing regulatory regime for the assessment and approval of biotech products for environmental release and for food safety purposes.

- (b) **May the phrase "sanitary and phytosanitary regulations which have been adopted" be interpreted to encompass also sanitary and phytosanitary regulations which have been adopted *de facto* (*e.g.*, generally applicable decisions which have been reached informally and which are unrecorded)?**

55. Yes. This is precisely the purpose of Article 7 and Annex B of the *SPS Agreement*. As the Appellate Body stated:

The object and purpose of paragraph 1 of Annex B is 'to enable interested Members to become acquainted with' the sanitary and phytosanitary regulations adopted or maintained by other Members and thus to enhance transparency regarding these measures. In our opinion, the scope of application of the publication requirement of paragraph 1 of Annex B should be interpreted in the light of the object and purpose of this provision.³⁵

56. If the provision were to be given a more restrictive scope, for example, by only including measures that had been formally adopted (*de jure*), WTO Members could easily evade their

³⁴ Canada First Written Submission, paras. 246-253.

³⁵ *Japan – Agricultural Products II*, Report of the Appellate Body, para. 106.

obligations under Article 7 and paragraph 1 of Annex B by structuring their decision-making in such a way as to avoid formal decisions with respect to SPS measures. This would be contrary to one of the central principles underlying the WTO Agreement as a whole, that is, the promotion of transparency with respect to all measures affecting trade. The EC would be able to claim that, because the *moratorium* was not formally adopted via a decision of one of the Community organs, there was no obligation on the EC to notify the moratorium or to publish it promptly. Such an argument would be completely at odds with both the letter and the spirit of the WTO rules.

142. Please explain the meaning and rationale of the requirement in Article 2.2 that SPS measures be "based on scientific principles" and how this is different from the requirement that SPS measures not be maintained "without sufficient scientific evidence".

57. Generally speaking, the reference in Article 2.2 to "scientific principles" relates to the methodological soundness and rigour of the process whereby the "scientific evidence" relied upon to support the measure in question is adduced. "Scientific principles" are reflected to some degree reflected in the requirements set out in Articles 5.1 through 5.3 and in the definition of "risk assessment" found in paragraph 4 of Annex A.

58. "Scientific" is, in relevant part, defined as "of, pertaining to, or of the nature of science" and "valid according to the objective principles of scientific method".³⁶ "Science" is defined as "a branch of study that deals either with a connected body of demonstrated truths or with observed facts systematically classified and more or less comprehended by general laws, and which includes reliable methods for the discovery of new truth in its own domain".³⁷ "Principle" has a variety of meanings, the most relevant definitions being "a fundamental truth or proposition on which others depend" and "a general or inclusive theorem or law, having numerous special applications across a wide field".³⁸

59. The foregoing suggests that "scientific principles" as used in Article 2.2 relates to the use of scientific methods of analysis, such as empiricism, objectivity, peer review and falsifiability (hypotheses can be tested and previous results verified or refuted). It is important that the data and other information put before the risk assessor is free from bias. In other words, it addresses the scientific rigour of the knowledge relied upon by the risk assessor. This can be distinguished from the term "scientific evidence", which focuses on the relationship between the conclusions of the risk assessment – rather than its conduct *per se* – and the risk management (SPS) measure selected.

60. To some degree, the notion of "scientific principles" is reflected in the requirements set out in Article 5.2 and 5.3 with respect to the conduct of the risk assessment, and in the definition of "risk assessment" found in Annex A. The two provisions specify, to a certain degree, the types of factors that must be included in the risk assessment, and the definition establishes the rigour that must be observed in its conduct.

143. The Panel notes a number of instances where the same or a related product was apparently submitted under separate applications for approval. This appears to be the case for Monsanto Roundup Ready oilseed rape GT73 (EC-70, EC-79); Syngenta Bt 11 maize (EC-80, EC-92, and related EC-69); Pioneer/Dow AgroSciences Bt corn Cry1F (1507) (EC-74, EC-75, EC-95); Monsanto Roundup Ready corn NK603 (EC-76, EC-96); Monsanto Roundup Ready corn GA 21 (EC-78, EC-85, EC-91); and the various "stacked" products. To what extent does the assessment by a lead CA, the relevant EC Scientific Committee and any information

³⁶ *The New Shorter Oxford Dictionary*, vol. 2 (Oxford: Clarendon Press, 1993), p. 2717. (Exhibit CDA-203)

³⁷ *Ibid.*

³⁸ *Ibid.*, p. 2356. (Exhibit CDA-204)

provided by a notifier under one application serve as a basis for consideration of another application for the same or a related product?

61. There are many cases in which the data provided by the notifier in support of applications under both the *Directives 2001/18* (and *90/220*) and *Regulation 258/97* is fundamentally similar. For instance, in relation to risk assessments for food, feed or environmental release, the molecular characterization data, including data regarding the inserted gene, the nature and level of proteins expressed by that gene, the toxicology or allergenicity of the new expressed proteins, is essentially the same. Consequently, the assessment of a product by one scientific committee could have and should have served as a basis for consideration of another application for the same or related product to the extent that the risks being assessed were the same or similar.

144. The Panel notes that a number of products containing the same transgenic modifications as products at issue in this dispute were previously approved by the European Communities prior to July 1998 (eg, swede rape tolerant to glufosinate ammonium (MS1, RF1) and (MS1, RF2); swede rape tolerant to glufosinate ammonium (Topas 19/2); maize tolerant to glufosinate ammonium (T25); maize expressing the Bt cry1A(b) gene (MON 810); maize tolerant to glufosinate ammonium and expressing the Bt cry1A(b) gene (Bt-11); soybean tolerant to glyphosate; chicory tolerant to glufosinate ammonium; maize Roundup Ready NK603). To what extent and how were the previous assessments of potential risks to human, animal or plant health and/or the environment associated with these transgenic modifications taken into consideration in the evaluation of potential risks arising from the products at issue before the Panel?

62. This question highlights the extent to which the products with pending applications are similar to products that have already been approved by the EC in terms of their genetic modification. Indeed, the range of transgenic modification in currently commercialized products is very limited (tolerance to specific herbicides and the expression of specific toxins). These transgenic modifications, and their associated potential risks, are well-understood.

63. To the extent that there are similarities between different products with the same transgenic modification, such as the transformation method used, the type of protein expressed, the plant biology, the end use to which the product will be put, the previous risk assessments evaluating these elements are relevant to and should have been taken into consideration in the evaluation of the potential risks arising from the products at issue before the Panel. For instance, where the toxicology of the expressed protein had already been examined for one product (*e.g.* soybean tolerant to glyphosate or oilseed rape Ms1xRf1 and Ms1xRf2 tolerant to glufosinate ammonium), this should have simplified considerably the toxicological evaluation where the same protein was expressed by a second product (*e.g.* NK603 maize and Ms8xRf3 oilseed rape, respectively).

64. In the evaluation of potential risks arising from the products at issue before the Panel, the EC does not appear to have given much weight to the previous assessments of potential risks associated with these transgenic modifications undertaken by its own scientific bodies. Had credible scientific evidence existed to bring into question the scientific conclusions regarding the previously approved products, one would have expected the EC to have revoked the approval of these products. In no case did the EC do so. Indeed, where EC Member States adopted safeguard measures, in no case did the EC consider the additional information put forth by the Member State in attempting to justify its safeguard measure sufficient to warrant the revocation of the initial approval.

For all complaining parties:

145. With reference to para. 7 of the European Communities second oral statement, is it "for the Complainants to rebut this evidence [submitted by the European Communities] by putting forward arguments and evidence as to why reasons for delays put forward in the European Communities' submissions are unjustified"?

65. Canada disagrees. Canada and the other complainants have established a *prima facie* case that the *moratorium* and *product-specific marketing bans* are not based on a risk assessment contrary to Articles 5.1 and 2.2 of the *SPS Agreement* and that the resulting delay in processing applications under the EC's approval regime for biotech products is undue contrary to Annex C. The onus shifts to the EC to demonstrate that the *moratorium* and *product-specific marketing bans* are either (a) based on a risk assessment or (b) justified under Article 5.7. The EC cannot do the former because there is no risk assessment upon which the bans can be based and has not even advanced an argument in relation to the latter.

66. In terms of undue delay, Canada has demonstrated that there has been undue delay in the completion of the approval procedures for all specific products of interest to Canada. In fact, the chronologies for individual applications, rather than refuting the *prima facie* case established by Canada, confirm the validity of Canada's arguments regarding the *moratorium* and resulting *product-specific marketing bans*.

For Canada:

147. With reference to exhibit CDA-118, how does this exhibit support Canada's assertion at para. 38 of its rebuttal?

67. The second sentence of paragraph 38 should read: "[a]t a 28 January 2003 meeting of the Agriculture Ministers, several Member States stated their opposition to lifting the moratorium until the regulations on genetically modified food and feed were adopted." In terms of traceability and labelling, Canada refers the Panel to paragraphs 29 and 30 of its Second Written Submission, and exhibits referred to therein, for support for the assertion that EC Member States continued to refuse to lift the *moratorium* until new legislation regarding traceability and labelling was in place.

148. Please explain your contention, in paragraph 73 of your Third Written Submission, that "in the only instance where an EC member State raised concerns about "biogeochemical cycles", the concern was not pursued."

68. On 14 March 2000, the EC Member State in question, Italy, made identical requests for more information on "biogeochemical cycles" in relation to both oilseed rape Falcon GS40 and Ms8xRf3. Indeed, the documentation provided by the EC in relation to each request is identical – see Exhibits EC-62 – attachment 95 and EC-63 – attachment 87. Given that the two products, Falcon GS40 and Ms8xRf3, both oilseed rape cultivars with a transgenic modification conferring tolerance to glufosinate-ammonium, were being assessed in parallel, Canada considers the Italian requests, made on the same date in relation to oilseed rape products with the same transgenic modification, to be a single request.

69. The notifier's response to the Italian request, sent on November 13, 2000,³⁹ was transmitted to all EC Member States.⁴⁰ The notifier explained that the proteins that confer tolerance to glufosinate-

³⁹ Exhibit EC-63 – attachment 88. Also, see Exhibit EC-62 – attachment 97.

⁴⁰ Exhibit EC-63 – attachments 89 and 90.

ammonium (the PAT enzyme) are highly specific and hence there is no reason to expect that the product would have any impact on biogeochemical cycles.⁴¹ Following receipt of this response, it does not appear that the any Member State disputed the notifier's explanation or raised additional concerns in relation to "biogeochemical cycles". Two years later, the notifier re-stated its conclusion in this regard in its revised environmental risk assessment submitted pursuant to *Directive 2001/18*.⁴² Again, the relevant EC authorities do not appear to have disputed this specific conclusion.

70. Canada is unaware of any other specific request for information concerning "biogeochemical cycles" in relation to a specific pending application.

For Canada, European Communities and the United States:

168 (EC-72). The Panel notes that the chronology provided by the European Communities shows no actions on this application between 12/99 (when according to the European Communities the UK CA allegedly advised the company that the dossier required substantial revision and clarification) and its re-submission in 1/03 under Directive 2001/18. Could the parties please explain the lack of action?

71. Canada has not made any claims in relation to this particular product – oilseed rape T45 and accordingly is not in a position to comment on this application.

⁴¹ Exhibit EC-63 – attachment 88.

⁴² Exhibit EC-63 – attachment 112, p. 40.

ANNEX F-5

REPLIES BY CANADA TO ADDITIONAL QUESTIONS POSED BY THE PANEL
IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
11 MARCH 2005

For all parties:

170. With reference to EC Directive 2001/18, Annex II, Section C.2.1, please indicate for each of the listed potential adverse effects of GMOs whether measures applied to prevent or minimise such effects fall within the scope of Annex A(1) of the SPS Agreement, and if so, why. The parties are also invited to address Section D with the same question in mind.

1. Measures applied to prevent or minimize each of the following "potential adverse effects of GMOs," as set forth in *Directive 2001/18*, Annex II, Section C.2.1, fall within the scope of Annex A(1) of the *SPS Agreement*.

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 in Annex III B);
- disease to animal and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11 and II.C.2(i) in Annex II A, and B 7 and D 8 in Annex III B);
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

2. Measures to protect against these three types of adverse effects fall squarely within Annex A(1)(b) of the *SPS Agreement*, which refers to measures applied "to protect human or animal life or health ... from risks arising from ... toxins or disease-causing organisms in foods, beverages or feedstuffs." The "adverse effects" set forth above concern the potential that a GMO product could be toxic to or cause disease in (directly or by increasing susceptibility to disease) humans or animals, which are the same risks as those enumerated in Annex A(1)(b). This conclusion is confirmed by each of the following information requirements for GMO notifications referenced in the first two provisions above: (1) item II.A.11 in Annex III A, which relates to "pathological traits" of GMOs, including "infectivity, toxigenicity, virulence [and] allergenicity," (2) item II.C.2(i) in Annex III A, which relates to "considerations for human health and animal health," arising from the compromised clinical efficacy of such antibiotics including "toxic or allergenic effects" of GMOs, (3) item B 7 in Annex III B, which relates to "potential interactions, relevant to the GMO...including information on toxic effects on humans," and (4) item D 8 in Annex III B, which relates to "toxic, allergenic or other harmful effects" arising from GMO crops when used for "animal feedstuffs." For these reasons, measures to address these effects fall within the Annex A(1)(b) of the *SPS Agreement*.

3. Measures to prevent the second and third types of adverse effects above also could fall within Annex A(1)(a) of the *SPS Agreement*, which refers to measures applied "to protect animal or plant life or health ... from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms." A measure falls within this provision if the adverse effects to animal health against which the measure seeks to protect arise from exposure to a GMO product other than a feedstuff.

4. Annex II, Section C.2.1 also includes the following "adverse effects":
- effects on the dynamics of population species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);
 - effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex A, and D 11 in Annex III B).

5. Measures to prevent these two types of adverse effects fall within the scope of Annex A(1)(a) of the *SPS Agreement*, which refers to measures applied "to protect animal or plant life or health ... from risks arising from the entry, establishment or spread of pests," or Annex A(1)(d) of the *SPS Agreement*, which refers to measures applied "to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests." Each of these adverse effects concerns the impact of a GMO product as a "pest," which the *SPS Agreement* defines to include "weed." More specifically, these adverse effects refer to the risk that a GMO product becomes a "weed," that is, a persistent and invasive plant that grows in environments where it is not wanted and overtakes other plant species, raising broader ecological concerns.¹ The adverse effects, therefore, relate to "other damage" caused by the "entry, establishment or spread of pests." This conclusion is confirmed by the following information requirements for GMO notifications referenced in the two provisions above: (1) items IV B 8 in Annex III A, which relates to the "potential for excessive population increase in the environment," and (2) item IV B 9, which relates to the "competitive advantage of the GMOs in relation to the unmodified [organisms]." Accordingly, measures to prevent or minimize these adverse effects fall within the scope of Annex A(1)(d) of the *SPS Agreement*.

-compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);

6. Measures to prevent such adverse effects fall within the scope of Annex A(1)(a) of the *SPS Agreement*, which refers to measures applied "to protect animal or plant life or health ... from risks arising from the entry, establishment or spread of...diseases, disease-carrying organisms or disease-causing organisms." If the antibiotic marker gene compromises the clinical efficacy of antibiotics used to protect animal life or health, then the measure would fall clearly within Annex A(1)(a).²

7. To the extent that the antibiotics in question are used to treat diseases arising from "disease-causing organisms" found in food, beverages or feedstuffs, the risks to human and animal life or health arising from the compromised clinical efficacy of such antibiotics would be covered by Annex A(1)(b). To the extent that the antibiotics in question are used to treat diseases in humans arising from "diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests", the risks to human life or health arising from the compromised clinical efficacy of such antibiotics would be covered by Annex A(1)(c).

¹ See Canada Answers to Panel Questions (7 March 2005), Question 120, paras. 10, 11.

² See Canada Answers to Panel Questions (16 June 2004), Question 40, para. 74.

171. In *Japan – Apples*, the Appellate Body interpreted Article 5.7 of the SPS Agreement and notably the phrase "in cases where relevant scientific evidence is insufficient". It stated at para. 179 that:

Article 5.1 [...] informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a "more objective assessment of risks". These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*. [...] The question is whether the relevant evidence [...] is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.

In this regard, please answer the following questions:

- (a) Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*"? Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?**

8. Canada is not sure that it fully understands the nature of the Panel's question, but it will do its best to respond to what it believes the question to be.

9. Yes. It is possible that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment as required under Article 5.1 and as defined in paragraph 4 of Annex A. In the quoted passage, Canada understands the Appellate Body to be indicating that the threshold for a finding that the "relevant scientific evidence is insufficient" and that Article 5.7 therefore might be applicable is linked to the obligation to perform a risk assessment found in Article 5.1. Thus, it is only when the relevant scientific evidence is insufficient to perform a risk assessment as required by Article 5.1, and as defined in Annex A(4) of the *SPS Agreement*, that Article 5.7 can be successfully invoked. Earlier in the paragraph, the Appellate Body refers to Article 5.1 as a "key discipline". The Appellate Body's reference to the phrase "a more objective assessment of risk" implies a connection between this phrase and a risk assessment as defined in Annex A(4). Hence, the two questions posed in paragraph (a) are in reality two sides of the same coin, with the *proviso* that Canada doubts that there is such a thing as a "fully objective" risk assessment. Risk assessments, like all processes of observation and evaluation involving human beings, inevitably involve a certain amount of subjectivity.

- (b) Does the phrase "more objective assessment of risks" in Article 5.7 support the view that a provisional measure adopted in accordance with Article 5.7 must be based on risk assessment, as required by Article 5.1? (Canada may wish to elaborate further on what it has already said in its supplementary rebuttal in relation to this point.)**

10. The structure and relationship between Articles 2.2, 5.1 and 5.7 suggest that the phrase "a more objective assessment of risk" in Article 5.7 refers to a risk assessment as defined in Annex A(4).

However, this does not mean that the initial "measure adopted in accordance with Article 5.7" must be based on a risk assessment of the same standard as that required by Article 5.1. That would be contrary both to the logic underlying Article 5.7, and the text of that provision, which refers to the adoption of a measure "on the basis of available pertinent information". As Canada has already argued, the reference in the second sentence of Article 5.7 to a "more objective" assessment of risk implies that "on the basis of available pertinent information" means that a risk assessment of some form must be carried out, even if it does not meet the standard set out in Annex A(4).³ It is also clear from the context that the "available pertinent information" refers to scientific information concerning risks to human, animal or plant life or health.

11. Furthermore, the text of Article 5.7, as well as logic, suggests that the phrase "a more objective assessment of risk" means a risk assessment of a standard that will enable the Member concerned to shift the legal basis for its measure, unless it repeals it entirely – from Article 5.7 to Articles 5.1 and 2.2. This inference is supported by the following considerations. First, measures of the type covered by Article 5.7 must be adopted provisionally. Second, a duty is imposed on the WTO Member concerned to "seek to obtain the additional information necessary for a more objective assessment of risk". Third, the Member concerned is required to review its measure according to the "more objective assessment of risk". In other words, the initial, or provisional, measure is intended to be a temporary solution while the Member gathers the scientific evidence necessary to complete a risk assessment that meets the standard set out in Article 5.1 and Annex A(4).

172. Annex A(1) of the SPS Agreement suggests that "approval procedures" are SPS measures. When a Member decides to delay the completion of such an approval procedure for a number of days, would such action be another SPS measure within the meaning of Annex A(1), or would such action rather need to be characterized as an application of an SPS measure (the application of the approval procedure)?

12. Canada refers the Panel to Part VII of Canada's First Written Submission.

13. Canada understands the question to be: under what circumstances can a delay in the completion of an SPS approval procedure become an SPS measure. The answer, of course, depends on the factual circumstances.

14. First, Canada agrees with the Panel that approval procedures are SPS measures. Annex A(1) of the *SPS Agreement* not only suggests that they are SPS measures; it states it explicitly: "Sanitary and phytosanitary measures include all relevant...procedures including...testing, inspection, certification and approval procedures...".

15. Second, the scenario set out in the Panel's question differs considerably from the factual situation in the present case. Canada would agree with the proposition that, if a Member simply delayed making a final decision on the approval of a given product for a few days, and communicated this in clear terms to the applicant, explaining why it was delaying the decision, how much time was involved, and informed the applicant what, if anything, it could do to expedite the process, this appropriately would be characterized as "an application of an SPS measure", rather than a separate SPS measure.

16. However, that is not the situation in this dispute. In general, a delay in the completion of an SPS approval procedure becomes an SPS measure when the source of the delay supersedes the approval procedure as the measure that exerts effective control over subject matter of the approval procedure, in this case the product applications. The EC has decided not to decide. The *moratorium*

³ Canada Third Written Submission, para. 114.

is a conscious decision on the part of the EC not to approve biotech products for an unspecified period of time. The *moratorium* is a separate SPS measure, distinct from the approval procedure. Although the *moratorium* is inextricably linked to the approval procedure by virtue of its motivation, and through its effect on the approval procedure, the *moratorium* essentially renders that procedure irrelevant, in the sense that it prevented the biotech products with outstanding applications from being approved. In this light, the various product applications are subject not merely to a delay, but to decisions not to approve (which is not the same as a decision to reject) the products. These decisions, or *product-specific marketing bans*, are a direct consequence of the *moratorium*, but constitute separate SPS measures. They also represent strong evidence of the existence of the *moratorium*.

17. Furthermore, Canada draws the Panel's attention to Canada's answer to Panel Question 45, wherein Canada made the point that the EC's "decision not to decide", in many instances, can be equated with a complete denial to approve a given product.⁴ Given the limited commercial shelf-life of many of these products, a prolonged delay in approval – and by any reasonable measure delays of five years or more must be considered prolonged – has led to lost and irretrievable market opportunities. By the time these products receive approval, if they ever do, the market will have passed them by.

173. May the fact that existing approval legislation does not permit a Member to adopt certain risk management measures which that Member considers appropriate serve as a justification, for purposes of an analysis under Annex C(1)(a) of the SPS Agreement, for delaying approval procedures conducted pursuant to the existing legislation? Are the provisions of Article 27 of the Vienna Convention on the Law of Treaties relevant to such a situation?

18. To a degree, this question is related to the Panel's Question 48(f), and Canada refers the Panel to paragraph 98 of Canada's Answers to the Panel's Questions (June 16, 2004).

19. The issue is not whether the WTO Member considers the risk management measures appropriate, but whether the risk management measures (SPS measures) are justified in relation to the outcome of a risk assessment that meets the requirements of Article 5.1 and Annex A(4), and viewed in the light of the Member's appropriate level of protection. That is, in the words of the Appellate Body, "a panel has to determine whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment".⁵

20. If a risk management measure that is "sufficiently supported or reasonably warranted by the risk assessment" does not fall within the scope of the Member's "existing approval legislation" and no other risk management measure exists that would also achieve the Member's appropriate level of protection, and which falls within the scope of the approval legislation, then it may be justified for the Member concerned to delay approving the product until the approval legislation can be amended accordingly. In other words, it may not constitute "undue delay" within the meaning of Annex C(1)(a).

21. However, this conclusion must be subject to the *proviso* that the Member concerned is also under an obligation to make the necessary legislative changes "without undue delay" so as to be in a position to make a final decision as quickly as possible in the circumstances.

22. In the context of the above situation, Article 27 of the *Vienna Convention* would not be a relevant consideration to the extent that it is not a situation where a party to a treaty is failing to

⁴ Canada's Answers to Questions from the Panel, 16 June 2004, para. 86.

⁵ *EC – Hormones*, Report of the Appellate Body, para. 186.

perform its obligations. The scenario described in Canada's answer is one where the party is acting in a manner consistent with its treaty obligations, once again, subject to the *proviso* that it must make the necessary legislative changes as quickly as possible in the circumstances.

23. If, on the other hand, the risk management measure in question is not sufficiently supported or reasonably warranted by a risk assessment that meets the requirements of Article 5.1 and Annex A(4) or the existing legislation allows for the imposition of the risk management measure in question,⁶ any delay in the completion of an approval procedure in order to make legislative changes to allow such a risk management measure to be adopted in a manner consistent with the Member's internal law would be undue, and Article 27 of the *Vienna Convention* would apply.

174. With regard to Article 2.2 of the TBT Agreement:

- (a) **Please explain the phrase "the risks non-fulfilment [of a legitimate objective] would create" and illustrate using an example.**

24. The phrase "the risks non-fulfilment [of a legitimate objective] would create" can only be understood with reference to the underlying purpose of Article 2.2 of the *TBT Agreement*, which is the proscription of "unnecessary obstacles to international trade". Technical regulations can be unnecessary obstacles to international trade in several ways. Measures that are not related to a "legitimate objective", or that do not fulfill or materially contribute to the fulfillment of, a "legitimate objective", are unnecessary obstacles to international trade. If the objective is legitimate and the technical regulation fulfills it or materially contributes to its fulfillment, it can still be an unnecessary obstacle to trade if it is more trade-restrictive than is necessary. This would be the case if an alternative measure exists that would achieve the same objective and is less trade-restrictive. The requirement to "tak[e] account of the risks non-fulfilment would create" imposes an obligation of proportionality that is linked to the legitimate objective. In other words, whether a given measure is more trade-restrictive than is necessary depends, in part, on the specific risks being addressed. The nature and magnitude of the risks involved must be taken into account in determining how trade-restrictive a technical regulation can be without becoming an unnecessary obstacle to trade. In this context, the "risks non-fulfilment would create" means the risks that would be realized, in other words, the occurrence of adverse effects.

25. As an example, let us say that a technical regulation is designed to protect human beings from the risks arising from using a certain household chemical cleaning product. However, the hazards inherent in the chemical are mild; although the chemical has toxic properties, it does not cause any serious acute impairment of health, nor does it give rise to any chronic negative health effects. At most, upon inhalation or ingestion at a given dose, a person might suffer from a mild headache and nausea that passes quickly. To seek to prevent even these negative effects, the regulator has several choices: it can require labelling to warn prospective users; it can require the concentration of the chemical to be so low that the adverse effect is essentially neutralized, keeping in mind that the higher the concentration, the more effective the cleaning product is; and/or it can require a child-proof cap and spraying mechanism. It can also ban the use of the chemical for this purpose. In this scenario, the objective is legitimate and all of the proposed measures either fulfill or materially contribute to the fulfillment of the objective. Some are more trade-restrictive than others. The determination of whether any one measure is "more trade-restrictive than necessary to fulfil [the] legitimate objective" has to take into account the risks – identified above as being fairly mild – that non-fulfilment of the legitimate objective would create.

⁶ Canada Second Written Submission, Part II.B.1 and 2.

(b) Article 2.2 refers to "scientific information" which must be taken into account in assessing risks. Article 5.2 of the SPS Agreement, on the other hand, refers to "scientific evidence". Are these different concepts? Why?

26. The difference between "scientific information" and "scientific evidence" can be seen in the ordinary meanings of the words "information" and "evidence." The ordinary meaning of "information" is "[k]nowledge or facts communicated about a particular subject, event, etc."⁷ The ordinary meaning of "evidence" is "facts or testimony supporting a conclusion, statement or belief".⁸ It is logical that the SPS drafters would use the term "scientific evidence" in an agreement where a core obligation is to base SPS measures on a scientific risk assessment. This obligation requires WTO Members to provide specific factual support that meets a higher standard of quality and reliability, that is, "evidence", for their SPS measures. The specific reference to "scientific evidence" in Article 5.2 is a reflection of the requirements of Article 2.2 that a measure not be maintained without sufficient scientific evidence, and the definition of a risk assessment in Annex A(4).

27. The *TBT Agreement*, by contrast, does not require, as an explicit obligation, that technical regulations be based on a risk assessment. TBT drafters used the term "scientific information" in respect of an obligation that requires Members to take account of scientific facts, where they are relevant to the selection of a particular measure. However, the *TBT Agreement* does not necessarily require those facts, as a matter of legal obligation *per se*, to be of a quality commensurate with that inherent in a risk assessment as defined in the *SPS Agreement*. In basic terms, the distinction between "scientific evidence" in Article 5.2 of the *SPS Agreement* and "scientific information" in Article 2.2 of the *TBT Agreement* relates to the differences in the respective obligations of the two agreements for measures to have a factual and/or scientific basis.

28. This does not mean, however, that a technical regulation would never need to be based on a full risk assessment. It is quite possible, in Canada's view, that some types of technical regulations will need to be based on a full risk assessment, and that, as a matter of an evidentiary burden, the WTO Member whose technical regulation is in issue will not be able to demonstrate that its measure is in fact based on such a risk assessment. Whether a technical regulation, as a matter of fact, needs to be based on a risk assessment can only be determined on a case-by-case basis.

29. In the particular case of the *product-specific marketing bans* and the *EC Member State national measures*, risk assessments are necessary in order for demonstrate that these measures are indeed not more trade-restrictive than is necessary to achieve a legitimate objective, taking into account the risks that non-fulfilment would create. As Canada has already demonstrated,⁹ there is no evidence to support the need for complete bans on either the biotech products of interest to Canada that are subject to the *product-specific marketing bans*, or the biotech products that are subject to the *EC Member State national measures*.

175. Are measures applied to ensure co-existence of biotech crops and non-biotech crops covered by Annex A(1) of the SPS Agreement or do they fall, in whole or in part, outside of the scope of Annex A(1)?

30. Canada understands co-existence to be about reducing the unintended admixture of biotech and non-biotech seeds or crops. In the EC, the intentional or adventitious presence of biotech

⁷ The New Shorter Oxford Dictionary, vol. 1 (Oxford: Clarendon, 1993), p. 1364. (Exhibit CDA-205)

⁸ *Ibid.*, p. 867. (Exhibit CDA-206)

⁹ Canada First Written Submission, paras. 337-352 and 486-499.

products above a prescribed threshold triggers the need for crops to be labelled as containing GMOs.¹⁰ This is a requirement that has been imposed by EC legislation. The consistency of this legislation with the EC's WTO obligations has yet to be determined and is not an issue in this case. What is in issue, however, is whether the absence of EC measures relating to co-existence can be a legitimate reason for delaying an SPS approval procedure.¹¹

31. A distinction must be made between risks to plant life and health arising from the admixture of biotech and non-biotech seeds or crops and the "potential *economic impact*" arising from the imposition of labelling requirements. A measure applied *for the purpose* of protecting plant life or health from risks arising from the admixture of biotech and non-biotech seeds or crops would fall within the scope of Annex A(1)(a) or (d) of the *SPS Agreement*. For example, where a biotech product could be considered a "pest" for purposes of the *SPS Agreement* (e.g. if the biotech crop had traits that conferred greater fitness resulting in enhanced "invasiveness" or "weediness"¹²), the *economic impact* of introduction of such pest could be considered "other damage" within the scope of Annex A(1)(d) of the *SPS Agreement*. On the other hand, a measure applied solely to reduce or prevent the "potential *economic impacts*" of the admixture of biotech and non-biotech products resulting from the imposition of labelling thresholds for biotech products would not fall under the *SPS Agreement*.

32. Were the EC's co-existence measures adopted *solely* to reduce or prevent the "potential *economic impacts*" of the admixture of biotech and non-biotech products resulting from the imposition of labelling thresholds for GM products, the pertinent question in this case would be whether or not the economic aspects of co-existence can be a legitimate justification for delaying indefinitely an SPS approval procedure. In Canada's view, concerns about co-existence, arising from labelling thresholds for marketing purposes, cannot serve as a legitimate reason for delaying an approval procedure under the *SPS Agreement*. For instance, the adoption of future measures to enhance consumer or producer choice (e.g. a quality grading system for canned vegetables or labelling purely for consumer information purposes) would not be a legitimate justification to delay the approval of a product under an SPS approval procedure pursuant to Annex C(1)(a). As the panel concluded in *Indonesia – Autos*, "the obligations contained in the *WTO Agreement* are generally cumulative, can be complied with simultaneously and ... different aspects and sometimes the same aspects of [a measure] can be subject to various provisions of the *WTO Agreement*."¹³ Just as the panel in *Indonesia – Autos* found that compliance with one *WTO Agreement* would not excuse a Member from violating another *WTO Agreement*, so too must the Panel find here that EC must meet its obligations under the *SPS Agreement* even if another *WTO Agreement* were also to apply to the measure at issue.

33. Tellingly, the European Commission itself has stated that the economic aspects of co-existence must be distinguished from "the environmental and health aspects dealt with under *Directive 2001/18/EC*".¹⁴ It logically follows that the EC and its Member States cannot block approvals under *Directive 2001/18* on the basis of a putative "economic impact" of the admixture of

¹⁰ EC, *Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming*, C(2003), pp. 6 and 7. (Exhibit CDA-165)

¹¹ See the Belgian Competent Authorities' rationale for failing to approve Ms8xRf3, Exhibit EC-63 – attachment 167, p. 3.

¹² Canada Third Written Submission, paras. 68 – 75.

¹³ *Indonesia – Autos*, Report of the Panel, para. 14.56.

¹⁴ EC, *Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming*, C(2003), pp. 6 and 7. (Exhibit CDA-165)

biotech and non-biotech crops where no risks to human health and the environment have been identified. To do so, would not only violate the EC's obligations under the *SPS Agreement*, but would seemingly violate the EC's own internal law.

34. In any event, the EC itself has failed to distinguish between the economic aspects and the environmental health aspects of co-existence and has instead, when it suits its own purposes, attempted to distort an economic issue, of its own creation, into an issue concerning risks to the plant life and health.

35. Canada has demonstrated that the purposes of the *moratorium* and the *product-specific marketing bans* must be inferred from the context, that the declarations – repeated and consistent – of the EC Member States confirm that the purpose of the *moratorium* is to protect human health and environment from risks arising from biotech products, and that it is reasonable to infer the purpose of the *moratorium* and the *product specific marketing bans* is to protect against the same risks to human health and the environment against which the EC's approval legislation is intended to protect.¹⁵ In its First Written Submission, Canada demonstrated that the purpose of the legislation, as expressed in preambular language and in its legislative history, is the protection from risks of the type described in Annex A of the *SPS Agreement*.¹⁶ Similarly, the nine Member State national measures subject to challenge in this dispute fall within the scope of Annex A of the *SPS Agreement*.¹⁷

36. Throughout these proceedings, the EC has conceded that its measures are designed to address risks to human health and the environment. Indeed, in its First Written Submission, the EC entitled the relevant section "Possible harmful effects on human health and the environment."¹⁸

37. Yet in the face of the many statements by EC Member States and the overwhelming evidence that the EC's measures are SPS measures, the EC now comes before the Panel and appears to suggest instead that the measures were and are taken to address the economic risk to farmers arising from co-existence. As the economic risk to farmers as a result of the EC's own labelling legislation would not be covered by the *SPS Agreement*, the EC would have the Panel conclude that the measures are therefore not subject to the disciplines of the *SPS Agreement*.

38. Such a conclusion would be patently incorrect. The evidence presented by Canada during these proceedings and admitted by the EC in its own legislation demonstrates that these measures were taken to address the risks identified in Annex A of the *SPS Agreement*. That they might also be taken to address other policy objectives is not relevant to their coverage under the *SPS Agreement*. The drafters of the *SPS Agreement* could have written that an SPS measure was one that is applied "solely" or "primarily" or "chiefly" to one of the enumerated policy objectives. They did not do so. They provided that a measure that "is applied" to accomplish one of the enumerated policy objectives and that affects trade would fall under the scope of the *SPS Agreement*, as set forth in Article 1.

¹⁵ Canada First Written Submission, paras. 160-162.

¹⁶ *EC – Hormones*, Report of the Panel, para. 8.25. ("That the EC measures are, *inter alia*, "applied to protect human ... life or health" can be inferred from the preambles to, and legislative history of, [the relevant EC Directives].")

¹⁷ Canada First Written Submission, paras. 376-385.

¹⁸ EC First Written Submission, p. 14.

For all complaining parties:

178. Please indicate whether the following alleged effects of biotech products fall within any of the subparagraphs of Annex A(1) of the SPS Agreement:

- (a) **Environmental components of biodiversity "outside human, animal or plant life or health, such as the ecological complexes referred to in the Convention on Biodiversity" (EC rebuttal, para. 266).**

39. If humans, animals, and plants comprise the universe of living things and biodiversity is concerned with the diversity of living things, then it is difficult to understand what component of biodiversity is "outside human, animal or plant life or health." A measure taken to protect the "environmental components of biodiversity" certainly could fall within Annex A(1), depending on the type of risks against which the measure seeks to protect. Ecological processes, for instance, could fall within "other damage" under Annex A(1)(d). See Canada's Answers to Panel Question 120.

- (b) **"A predator insect eating another insect because it is itself growing better on a diet of Bt maize" (EC rebuttal, para. 266).**

40. It is unclear to Canada to what the EC is referring in para. 266 as the EC fails to identify any concrete example of this type of risk, much less identify a risk assessment conducted by one of its scientific committees where this risk is evaluated. In Canada's view, this is yet another example of the EC resorting to hypothetical concerns that bear no relationship to the actual risks posed by the biotech products in question. Such hypothetical concerns cannot serve to transform an SPS measure into a non-SPS measure.

41. In any event, "a predator insect eating another insect because it is itself growing better on a diet of Bt maize" would fall within "other damage...from the entry, establishment or spread of pests." If the introduction of a biotech plant facilitates the "spread of pests", the resulting damage could be considered "other damage from ... the spread of pests." The biotech product does not have to be the pest in issue.

- (c) **Human health risks arising from occupational exposure to a substance in a biotech product that is a toxin for insects (e.g., the Bt toxin) as opposed to risks arising from the consumption of the biotech product (EC rebuttal, para. 316). (The United States may elaborate on its response to Panel Question 73 or comment on the European Communities' response).**

42. Canada agrees with the response of the United States to Panel Question 73. A measure to protect humans against occupational exposures from Bt toxins in corn, which is consumed as either a food or feedstuff, are measures to "protect human or animal life or health from "risks arising from ... toxins ... in foods ... or feedstuffs" and are accordingly, subject to the *SPS Agreement*. Annex A(1)(b) does not specify or restrict the mode of exposure. Not surprisingly, the EC disagrees, suggesting that such a proposition might mean that "a heavy bar containing highly toxic concentrations of lead" would be subject to the *SPS Agreement*. As a "heavy bar" is unlikely to be consumed as a food or feedstuff, the EC example is simply specious.

43. Canada also notes that the Italian authorities have put forth no evidence of human health risks arising from occupational exposure to Bt toxins in maize or any other food for that matter. The study

that the Italians appear to rely on involved the application of Bt pesticides in spray form.¹⁹ This study did not appear to the Italian scientific experts to be relevant to the determination of the safety of Bt maize.²⁰ This is yet another example of the EC resorting to hypothetical concerns that bear no relationship to the actual risks posed by the biotech product in question, and which have already been rejected by its own scientists. Such hypothetical concerns cannot serve to transform an SPS measure into a non-SPS measure.

179. Please comment on the European Communities' statement that "for the purposes specifically of proving a 'moratorium' that applies across the board, it does not suffice to address only a limited selection of product applications" (EC rebuttal, footnote 212).

44. Canada does not agree. As Canada has stated on numerous occasions, the *moratorium* did not result in the complete shutdown of the EC biotech approval procedures. There was some progress made in respect of some applications. However, the *moratorium* meant that regardless of the merits of particular product applications, not a single decision was made by the EC to approve or reject a biotech product under the relevant approval procedures, not just for a "limited selection of products". The EC made a decision not to decide, or in other words, not to complete its approval procedures for all biotech products.

45. The complainants need not provide evidence of the status of each and every product application that is lodged at some point in the EC's approval procedures to establish the existence of a *moratorium* on the consideration of applications for, or granting of, approval of biotech products. Apart from the fact that not a single product application was either approved or definitively rejected between October 1998 and May 2004, Canada has provided ample evidence of the existence of the *moratorium* and the *product-specific marketing bans*, being the manifestation of the *moratorium* in the context of the approval procedures of the four specific products of concern to Canada. Having established a *prima facie* case, it is for the EC to refute the existence of the *moratorium* and *product-specific marketing bans*.

For Argentina and Canada:

180. In relation to antibiotic marker genes, please answer the following questions:

- (a) **Do you agree with the United States that antibiotic marker genes can be considered as food "additives" within the meaning of Annex A(1)(b) of the SPS Agreement (see para. 22 of attachment II of the US rebuttal)? If not, is the protection against any human health risks arising from the development of diseases which relevant antibiotics would be used to treat covered by another subparagraph of Annex A(1)?**

46. Canada is of the view that the United States' interpretation of the term "additive" is linguistically plausible. An antibiotic resistance marker gene is a "substance" in the basic sense of that term, and nothing in the Codex definition serves to exclude the possibility that an antibiotic resistance marker gene can be considered an additive. Canada also observes that the EC has not offered any concrete evidence or argumentation to refute the interpretive approach offered by the United States.

¹⁹ L. Bernstein et al., "Immune Responses in Farm Workers after Exposure to *Bacillus Thuringiensis* Pesticides" *Environmental Health Perspectives*, 107:575, 1999. (Exhibit CDA-201)

²⁰ Exhibit EC-157 – Attachment 002, pp. 6-7.

- (b) **Please comment on the European Communities' assertion that "there is concern about the development of antibiotic resistance in connection with 'plants' as such" (EC rebuttal, para. 64) and on whether a measure applied to address this concern would fall within the scope of Annex A(1).**

47. The phrase "there is concern about the development of antibiotic resistance in connection with 'plants' as such" is unclear. The absence of any kind of documentation or other supporting evidence contributes to the obscurity of the statement. If Canada understands the thrust of the EC's argument correctly, the EC is referring to the transfer of antibiotic resistance directly from plants to, presumably animals and humans. This seems to be borne out by the two preceding sentences, which suggest that antibiotic resistance may develop in humans and animals through uptake of antibiotic resistance genes through means other than food and feed. The EC does not explain specifically how this would occur, or why this "may" be an "important factor".

48. In any event, the EC's comment is not relevant to this dispute unless the source of this antibiotic resistance is materials from a transgenic plant carrying the antibiotic resistance marker gene (ARM) gene. To the extent that these ARM genes inadvertently find their way into food and feed, they might be considered contaminants and therefore Annex A(1)(b) would apply.

49. Canada also notes that this appears to be another of the EC's many hypothetical scenarios involving, at worst, a minute risk relative to the ready transfer of antibiotic resistance genes among bacteria, and relative to the emergence of novel resistance genes which are (a) increasingly frequent, and (b) have nothing to do with ARM genes in plants at all. The EC even admits in its Comments on the Scientific and Technical Advice that "since marker genes are the same as those already spread in nature, it is difficult to trace them."²¹ In such a case, it is difficult to see what risk they could pose.

181. With reference to Argentina's and Canada's claims in respect of the member State safeguard measures under Article 2.1 of the TBT Agreement, do the relevant safeguard measures apply to the relevant biotech products when imported into the territory of the relevant member States and when produced in the relevant member States, or do they apply only when the products are imported?

50. In the case of the two French bans, on oilseed rape Topas 19/2 and Ms1/Rf1, the ministerial decrees specify that commercialization is suspended, product shall be withdrawn from sale, and importation is prohibited.²² In the case of the Austrian ban on maize T25, the ordinance banned commercialization.²³ The Italian ministerial decree banning maize MON809, MON810, T25, and Bt11 specified that it was suspending the commercialization and utilization.²⁴

²¹ EC Comments on the Scientific and Technical Advice to the Panel (28 January 2005), para. 105.

²² France, Minister of Agriculture and Fishing, Decree of 16 November 1998 involving suspension of the commercialization of genetically modified colza by virtue of article 16 of directive 90/220/CEE of 23 April 1990, pursuant to decision 98/291/CE of 22 April 1998, J.O., 18 November 1998, 17379 (English translation and French original) (Exhibit CDA-64); France, Minister of Agriculture and Fishing, Decree of 16 November 1998 involving suspension of the commercialization of genetically modified colza by virtue of article 16 of directive 90/220/CEE of 23 April 1990, pursuant to decision 96/158/CE of 6 February 1996, J.O., 18 November 1998, 17379 (English translation and French original). (Exhibit CDA-68)

²³ Austria, Federal Minister of Social Security and Generations, Ordinance issued 28 April 2000 prohibiting the commercialization of the genetically altered corn Zea Mays L. T25 in Austria, approved by the European Commission on 22 April 1998 under Decision 98/293/EC, Federal Gazette, vol. 2000, 28 April 2000 (English translation and German original). (Exhibit CDA-76)

²⁴ Italy, President of the Council of Ministers, Precautionary suspension of the commercialization and utilization of certain transgenic products (Corn BT 11, Corn MON 810, Corn MON 809 and CORN T25) in the

51. In fact, with the exception of the Greek import ban, none of the measures specify that they apply only when the products are imported. Given the broad language used, it must be assumed that the measures apply to the relevant biotech products when imported into the territory of the respective Member States and when they are produced in those Member States.

For Canada and the United States:

182. Could Canada and the United States provide examples of why and how allergens in food can be said to "destroy[] life or injure[] health" (US rebuttal, attachment II, para. 27) or "destroy[] life or impair[] seriously the functions of organs or tissues" (Canada's supplementary rebuttal, para. 51)?

52. An allergen present in food can cause a variety of symptoms in individuals susceptible to that allergen. Some examples of food allergic reactions include angioedema (swelling and redness of the skin), urticaria (itchy hives), allergic rhinitis (runny nose), asthma, and anaphylaxis (a sudden and severe reaction characterized by a sudden drop in blood pressure and breathing difficulties that can be fatal). Thus, an allergen can "destroy life or impair seriously the functions of organs or tissues".

For Canada:

184. At para. 24 of Canada's second oral statement it is stated that if there is credible scientific evidence that the continued "processing" of applications under an existing approval regime would give rise to actual risks to human health or the environment, a suspension of an approval regime may be warranted.

(a) What does Canada mean by "processing" of applications? Their final approval?

53. Canada means the final approval of the product resulting in the placing on the market of the product.

(b) If so, and if there was scientific evidence of an actual risk, why should a Member not be expected, in the light of Annex C(1)(a) of the SPS Agreement, to complete its approval procedures and either grant marketing approvals subject to appropriate conditions, or to deny marketing approvals temporarily, with a possibility to review the continued justification of denying marketing approval once relevant circumstances change (e.g., the regulatory regime has been updated)?

54. Canada agrees that, if there was scientific evidence of an actual risk, a Member should, in the light of its obligations under Annex C(1)(a) of the *SPS Agreement*, complete its approval procedure and either grant marketing approvals subject to appropriate conditions, or to deny marketing approvals temporarily, with the view to reviewing the continued justification for denying the marketing approval once the regulatory regime has been updated. The type of circumstances to which Canada alluded in paragraph 24 of its Second Oral Statement are addressed in Canada's response to Question 173 above.

185. Canada's submissions on the alleged product-specific marketing bans are complex. At paras. 121 and 123 of its supplementary rebuttal, Canada says that "[i]n relation to the product-specific marketing bans, the measure at issue is the moratorium", even though Canada also maintains that the alleged bans are measures in their own right. Similarly, at para. 203 of its supplementary rebuttal, Canada says that "[i]n relation to the product-specific marketing bans, one of the central issues before this Panel is whether, in the light of the moratorium and given the resulting excessive delays in the processing of the applications in question, there was an effective 'political' decision on the part of the EC not to approve these products". These statements appear to suggest that the alleged product-specific marketing bans are the result of the alleged decision on the part of the EC to stop authorizing any biotech product (general moratorium). Later in the same submission, at para. 225, Canada argues that in respect of one particular product (Ms8xRf3), a marketing ban arose only in March 2000. And Canada suggests that any delay following that date was undue. In a similar vein, para. 192 of the same submission states that the alleged product-specific marketing bans have caused undue delay in the completion of the approval procedures for the relevant products. Is Canada arguing that the alleged product-specific bans, i.e., the measures it is challenging, may have been adopted after the alleged adoption, in 1998, of the decision to stop authorizing any biotech products (general moratorium)? And is Canada arguing that once the alleged bans were adopted, they gave rise to undue delays contrary to Annex C(1)(a) of the SPS Agreement?

55. The *product-specific marketing bans* are a direct consequence of the *moratorium* as applied to individual product applications. They are also proof of the *moratorium* and, for Canada, the most injurious manifestation of the *moratorium*.²⁵ They are however, distinct measures from the *moratorium* and give rise to distinct violations of the WTO Agreement. The arguments in relation to *product-specific marketing bans* are intended to focus on the direct and detrimental impact of the *moratorium* on specific product applications.

56. In principle, the adoption of the *moratorium* led to the adoption of the *product-specific marketing bans*. However, in some cases, it appears that the Commission attempted, unsuccessfully, to convince the EC Member States to lift the *moratorium*. In the case of Ms8xRf3, in order to give the Commission the benefit of the doubt in its attempt to break the *moratorium* and convince EC Member States to adopt the Commission so-called interim approach, Canada has indicated the alternative date of March 2000 as the date the *product-specific marketing ban* in relation to this product was unquestionably imposed.

57. Canada is arguing that the *product specific marketing bans* imposed on each product have caused undue delay in the completion of the approval procedures. In respect of each of the specific products, Canada has demonstrated specific instances of undue delay. The delay was not simply because of inadvertence or neglect, but because of a decision not to complete the approval procedure.

186. Please explain the contrast between Canada's statement that in determining whether a delay is undue within the meaning of Annex C(1)(a) of the SPS Agreement, both the reason for the delay and its duration must be taken into account (Canada's supplementary rebuttal, para. 188) and the assertion that "a delay of seven years in approving this product [...] is, by any reasonable standard, 'undue'" (Canada's second oral statement, para. 57 [similar statement at para. 63]).

58. To the extent that there is a contrast between Canada's statements in paragraph 238 of its First Written Submission and paragraph 188 of its Supplementary Rebuttal, and its assertions regarding the

²⁵ Canada First Written Submission, para. 255.

failure of the EC to approve the product applications for GT73 and Ms8xRf3 in paragraphs 57 and 63 of its Second Oral Statement, that contrast is more apparent than real.

59. As Canada noted in paragraphs 57 and 63 of its Second Oral Statement, these product applications have been in the system for approximately seven and nine years, respectively. In the case of GT73, if the time is counted from the date when the notifier first submitted its application to France, the amount of time that the product has been in the system actually rises to almost 10 years!²⁶ The length of time it has taken, so far, for these products to move through the approval system has to raise serious questions about whether the failure to make a decision amounts to undue delay, keeping in mind that they still have not been approved.

60. However, the amount of time these product applications have languished in the EC's approval procedure is not the sole reason for Canada's claim that the delays have been, by any reasonable standard, undue. First and foremost, the EC has had in place, since October 1998, a *moratorium* on the approval of new agricultural biotech products. The EC has failed to demonstrate why this across-the-board marketing ban on these products was necessary. Furthermore, in the case of each product application, Canada has demonstrated that the EC has not put forward a cogent rationale, based on scientific evidence, for why it has refused to approve these products. In other words, the refusal to approve these products is not based on a risk assessment, despite numerous favourable risk assessments conducted by the EC's own scientific committees. Canada has also demonstrated that the EC's refusal to approve these products amounts to an arbitrary and unjustifiable distinction in the application of its appropriate level of protection. It is for these reasons, as well, that the EC's failure to approve GT73 and Ms8xRf3 (as well as Ms1xRf1 and Ms1xRf2) is both excessive and unjustified, and therefore amounts to undue delay, contrary to paragraph 1(a) of Annex C and Article 8 of the *SPS Agreement*.²⁷

187. With reference to para. 76 of Canada's supplementary rebuttal, please clarify whether a measure applied to protect against risks to wild fauna from increased use of the herbicide associated with a biotech crop or another herbicide, due to the development of herbicide resistance, falls within the scope of Annex A(1) of the SPS Agreement. If so, please indicate the relevant subparagraph.

61. First, Canada would like to emphasize that the introduction of a biotech product does not necessarily result in the increased use of the associated herbicide. While herbicide-tolerant crops permit greater flexibility in application of the associated herbicide, (*e.g.* the application of the herbicide can be tailored to the actual weed pressure after the crop has emerged),²⁸ this does not imply that herbicide use will increase or that wild fauna will be affected. If one is concerned about increased herbicide use, one could impose restrictions on the use of the herbicide.

62. Second, the EC attempts to conflate risks associated with herbicide use with risks "arising from" biotech crops. At the same time, the EC attempts to rely on an artificial distinction about the cause of the risks to avoid compliance with the *SPS Agreement*. The EC is attempting to have it both ways – suggesting that the risks arising from the use of herbicides is a legitimate justification for denying approval of a biotech product while also suggesting that such risks do not "arise from" the introduction of the biotech product.

²⁶ Canada First Written Submission, para. 86.

²⁷ Canada First Written Submission, paras. 292-97.

²⁸ See for example Exhibit EC-63 – attachment 163.

63. Canada does not agree that the EC can have it both ways. Contrary to the EC's assertions,²⁹ the phrase "arising from" does not require that the risk be direct or immediate. If the biotech product qualifies as a "pest" that needs to be controlled with herbicides, any resulting risks to wild fauna "arise from" the pest. It is the presence of that pest that triggers the sequence of events that ultimately leads to damage to wild fauna, if any such damage actually exists (the absence of evidence of such a risk implies it is yet another purely speculative risk raised by the EC). Consequently, measures applied to protect against risks to wild fauna from increased or altered use of herbicides, would fall within either Annex A(1)(a) as measures applied to protect "animal [including wild fauna] life or health...from risks arising from the entry, establishment or spread of pests" or, for good measure, Annex A(1)(d) as measures applied to "prevent or limit other damage...from the entry, establishment or spread of pests."

188. Please comment on para. 14 of the European Communities' second oral statement. Does para. 20 imply that if the use of glufosinate-ammonium has not already been authorized in Belgium under the relevant pesticide legislation, the potential effects of its use is a justification for failing to grant approval of MS8xRF3 (see paras. 235, 240 and 246 of Canada's supplementary rebuttal)? In this context, please also address the EC assertion that "the use of the herbicide may affect the composition of the food or feed resulting from the HTGM crop as compared with its non-GM equivalent" (EC second oral statement with regard to expert meeting, para. 11).

64. Canada understands that when the Panel refers to paragraph 20 of the EC's Second Oral Statement it intended to refer to paragraph 14. Paragraph 20 does not appear to relate to this issue.

65. In paragraph 14, the EC stated "as can be seen from the authorisation cited in footnote 208 of Canada's supplementary rebuttal submission, that authorisation is for a different use (seed production only) for a different transformation event (MS1xRF2)." The EC claims that this has no relevance to the authorization for Ms8xRf3. This assertion is without foundation.

66. First, "seed production" refers to the use to which the seeds may be put.³⁰ Regardless of the end use of the seeds (whether for seed production, human food or animal feed), one still has to grow the crop. The end use of the seeds has no effect on the use pattern of the herbicide (timing, application method, frequency, dosage etc) and consequently no impact on the risks to the environment from the use of the herbicide. The EC's attempt to dismiss the relevance of this herbicide authorization on the basis that it involves "seed production" is devoid of logic.

67. The authorization of glufosinate ammonium was limited to seed production because at the time it had yet to be assessed for food and feed purposes. As the Belgian scientific experts, reviewing the application for approval of Ms8xRf3, observed:

In 1996, questions were raised concerning the lack of toxicological tests for the metabolites and residues derived from glufosinate ammonium herbicides. At that time, the use of glufosinate ammonium as a total herbicide was authorized in Belgium, but not the use of the herbicide on herbicide-tolerant plants. For this reason, AgrEvo handed in a dossier for the broadening of the use of the herbicide 'Liberty' under the Directive 91/414/EEC. The risk assessment of the herbicide use

²⁹ EC Rebuttal Submission, para. 63.

³⁰ See for example *Commission Decision 96/158/EC*, authorizing oilseed rape Ms1xRf1. That *Decision* limited the consent to "cover the notified use of the product for growing for obtaining seed, but does not extend to the use for human food or animal food, without prejudice to any future assessment of the product for such use." Exhibit CDA-62, p. 2, para. 2(b).

and thus the toxicity of glufosinate ammonium and metabolites were assessed by the Belgian Health Council within the framework of the plant protection products Directive 91/414/EEC. End 2000 [sic], the Health Council gave a positive opinion for the use of glufosinate ammonium on herbicide-tolerant plants. The final authorization of the Ministry is not yet granted.³¹

68. Thus, the use of herbicide for other uses has now been assessed, although the final authorization has yet to be granted. Perhaps the EC could provide the Panel with a copy of the Health Council's positive opinion and explain why the Ministry has not yet granted final authorization.

69. Second, in terms of the EC's attempt to dismiss the relevance of the herbicide authorization on the basis of a "different transformation" event, the Belgian authorization for glufosinate-ammonium for use on genetically modified oilseed rape does not limit the application of the herbicide to a specific transformation event.³² To the contrary, the herbicide authorization merely states "for genetically modified oilseed rape." The statement by the Belgian scientific experts quoted above supports the conclusion that the authorization for the use of the herbicide glufosinate ammonium is for oilseed rape generally and is not limited to a single transformation event. Yet again, the EC appears to be advancing specious claims.

70. In any event, the potential impact on the environment or "biodiversity" from the use of the herbicide with oilseed rape Ms1xRf2 is equivalent to the use of that herbicide with oilseed rape Ms8xRf3. The only significant difference between Ms8xRf3 and Ms1xRf2 is that Ms1xRf2 contains the *nptII* antibiotic resistance marker gene, while Ms8xRf3 does not. Consequently, the different transformation event has no impact on the pattern of use of the herbicide or potential risks to the environment.

71. Paragraph 14 of the EC Second Oral Statement should be seen for what it is – a groundless attempt to confuse in order to distract the Panel from the Belgian authority's patent inconsistency of basing its failure to approve Ms8xRf3 on the putative risks from herbicide use while Belgium's own pesticide authorities expressly authorized the herbicide for use with GMHT oilseed rape.

72. With that as background, Canada will now respond to the Panel's Question. The absence of the authorization of a particular herbicide use cannot serve as a justification for refusing to grant approval for a biotech product. As the EC has recognized on numerous occasions, the approval of the biotech product is independent of the approval of the use of chemical herbicides.³³ The Belgian scientific experts also recognized that the risks associated with herbicide use are assessed by the relevant pesticide authorities under *Directive 91/414/EEC*.³⁴ Risks arising from the use of the herbicide should not be considered as legitimate reasons for denying the approval of a HT biotech product. The two are not related given that the risks arising from herbicide use are influenced by numerous variables independent of the crop itself (application method, dosage, timing, frequency of application etc.). Conflating the two provides a convenient pretext for disguising the fact that the EC is imposing a dramatically higher level of scrutiny and level of protection for herbicide use associated with biotech products than for herbicide use generally. This is yet a further example of, what Dr. Squire describes as the EC's "inconsistency" in terms of scrutiny of agricultural practices.

³¹ Expertise Report of the Group of Experts Mandated by the Biosafety Advisory Council, Exhibit EC-63 – attachment 167, p.18, Section 3.8.2 "Residue Assessment".

³² Canada Third Written Submission, para. 246, footnote 208, Exhibits CDA-152 and 160.

³³ Canada Third Written Submission, para. 240 and footnote 199.

³⁴ Exhibit EC-63 – attachment 166, p. 18.

73. In terms of the question regarding the impact of the herbicide on the composition of food and feed, Canada notes that the "food" derived from oilseed rape is oil. The oil has been notified for food use in the EC since 1999 as being substantially equivalent to conventional oilseed rape.³⁵ Had there been compositional changes in the oil as a result of the use of glufosinate-ammonium on the crop, presumably the oil could not have been notified as substantially equivalent. Alternatively, if this is a genuine risk the EC overlooked back in 1999 that has only now come to light, one would expect the EC to take some action to suspend the marketing of the oil. Tellingly, the EC has not because it has no scientific basis to do so.

74. In fact, the impact of the herbicide on the composition of the food and feed derived from oilseed rape tolerant to glufosinate-ammonium has been extensively reviewed by the EC's own scientific committees. The SCP reviewing Ms8xRf3 in May 1998 assessed the safety of the gene products, herbicide residues and metabolites.³⁶ The SCP specifically referred to the SCP opinion on oilseed rape Topas 19/2 in relation to the assessment of herbicide residues and the metabolites resulting from the interaction of the herbicide with the plant. There are two metabolites – one major metabolite (3-methylphosphinico-propionic acid (MPP)) and one minor metabolite (N-acetyl-glufosinate).³⁷ In the latter opinion, the SCP stated the following:

6.2.2. Safety of Gene Products/Metabolites (Food and Feed Aspects):

Safety of gene products: PAT protein is ubiquitous in nature but represents only 0.005% of protein in finished canola meal. It is heat and acid labile and the enzyme activity is always destroyed in toasted canola meal.

Additional in vitro tests demonstrated the inactivity of PAT and npt II in gastric juice of farm animals and it is hypothesised that it does not survive ingestion. In vivo tests performed on broiler chickens fed canola in their diets confirmed the safety established in rats with purified protein.

Data concerning the chemical analysis demonstrated substantial equivalence with control seeds for major nutrients including protein, oil, amino acids, fatty acids, tocopherols and sterols. The content of glucosinolates and erucic acid in glufosinate tolerant rape was identical with that of control seeds. Sequence comparisons show that PAT protein does not have homology to known allergens. Acute toxicity tests on PAT protein in rats showed no negative effects.

These results lead the Committee to conclude that there is no significant risk to human and livestock following ingestion of the GM seeds.

Residue assessment: The metabolism of glufosinate ammonium in transgenic plants, carrying the pat gene, has been thoroughly studied. The gene enables the plant to rapidly metabolise the herbicidal active moiety into a non-toxic metabolite, N-acetyl-L-glufosinate. The metabolism studies on genetically modified canola (rape) showed

³⁵ Canada First Written Submission, para. 78 and EC, Summaries of Article 5 notifications received by the Commission for the years 1997 [1998] O.J. C. 200/16, 1998 [1999] O.J. C. 181/22, 1999 [2000] O.J. C. 71/2, 2000 [2001] O.J. C. 46/8, 2002 [2003] O.J. C. 33/6, and 2003 [2004] O.J. C. 58/9, product No. 10. (Exhibit CDA-25).

³⁶ EC, Scientific Committee on Plants, Opinion regarding the Glufosinate tolerant, hybrid rape derived from genetically modified parental lines (MS8 x RF3) notified by Plant Genetic Systems (Notification C/B/96/01), submitted 19 May 1998, pp. 4-5. (Exhibit CDA-35-A)

³⁷ Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Glufosinate-Tolerant Rape Notified by Agrevo Company (C/UK/95/M5/1), (Exhibit CDA-63).

a rapid conversion of glufosinate to N-acetyl-glufosinate. In the immature canola plant the principal residue identified was N-acetyl-glufosinate followed by glufosinate with lesser quantities of 3-methylphosphinico-propionic acid (MPP). In seeds and hulls MPP was the major metabolite and the N-acetyl-glufosinate a minor metabolite.

Magnitude of residues in glufosinate tolerant rape seed: Many trials were conducted in various Canadian regions during 1992 and 1993 with different application rates. In no case were residues of the metabolite MPP found at levels above the limit of determination; residues of parent glufosinate were found only in one trial; N-acetyl-glufosinate was found in samples of 5 trials up to 0.14 mg/kg. The residue behaviour in tolerant oilseed rape processed fraction was also studied in a trial conducted in Canada. No detectable residues were found in crude/refined/refined bleached/refined bleached deodorised/oil. N-acetyl-glufosinate was found in soapstock at a concentration of up to 0.1 mg/kg after application at an exaggerated rate only.

Magnitude of residues in food of animal origin: Ruminant and poultry feeding studies were conducted to determine the magnitude of glufosinate-derived residues in the tissues and milk of dairy cows and in the tissues and eggs of chicken hens which were dosed for 28 consecutive days with a mixture of parent glufosinate and the metabolite N-acetyl-glufosinate in a ratio which represents the terminal residues in relevant animal feed (15% / 85%) at 3 dose levels. No detectable residues were found in meat, milk or eggs at the dose calculated to represent the highest residues in livestock feed under Good Agricultural Practice and taking into account the potential use of glufosinate herbicide in several tolerant crops.

Conclusion on residue assessment: On the basis of the available data, a maximum of 0.2 mg/kg of residues of glufosinate ammonium and its metabolites, N-acetyl-glufosinate and 3-methylphosphinico-propionic acid (expressed as glufosinate-free acid equivalents) can be calculated for imported seed of tolerant swede rape. In food of animal origin derived from livestock animals fed with feedstuffs after application of glufosinate herbicide in tolerant rape, no residues above the limit of determination can be expected. In Canada, the MRL for glufosinate-derived residues in tolerant canola is covered under the existing MRL of 3.0 mg/kg for canola from desiccation use (information by the applicant). The US EPA uses a Reference Dose of 0.02 mg/kg b.w. in the human dietary risk assessment for glufosinate-derived residues in commodities from non-transgenic plants as well as from transgenic plants (Federal Register, Vol. 62, No. 24, p.5333, 1997).

6.2.3. Substantial Equivalence: Compositional analysis on seed harvested from trials at a number of locations within Canada in several successive years provided data on oil content, fatty acid composition (including erucic acid content) and glucosinolate levels. Those for the seed from the genetically modified plants fall within the range for non-GM control varieties.

For food purposes the product is likely to be highly processed so that both the genetic material introduced into the transgenic plant and its protein products would be absent from the refined product.

On the basis of substantial equivalence, it can be concluded that refined products from plants derived from this glufosinate tolerant plant would be safe for food use.

75. Other EC scientific committees have also assessed the impact of glufosinate-ammonium on the composition of other types of food and feed (maize), finding no adverse effects.³⁸ Lastly, Canada recalls the statement of the Belgian scientific experts of January 2004 in the assessment of Ms8xRf3 quoted above:

The risk assessment of the herbicide use and thus the toxicity of glufosinate ammonium and metabolites were assessed by the Belgian Health Council within the framework of the plant protection products Directive 91/414/EEC. End 2000 [sic], the Health Council gave a positive opinion for the use of glufosinate ammonium on herbicide-tolerant plants. The final authorization of the Ministry is not yet granted.³⁹

76. In the light of the comprehensive assessment of the impact of glufosinate-ammonium on the composition of food and feed conducted by the EC's own regulatory authorities, for the EC to suggest that this issue is only "now" coming to light and has yet to receive such a comprehensive assessment is plainly disingenuous. More troubling is the failure by the EC to address, let alone refer the Panel to, the detailed analysis directly relevant to this issue undertaken by its own scientists. The EC's arguments in this regard are not only without scientific justification but are patently misleading and should be rejected.

189. At para. 254 of its supplementary rebuttal, Canada states that "[i]n the light of the moratorium, it is reasonable to infer that the regulatory authorities were taking a decidedly go-slow approach". The member State referred to in this statement is notably the Netherlands. Did Canada submit evidence that the Netherlands supported the alleged moratorium at the time it completed its initial assessment of GT73? If the Netherlands did not support the alleged moratorium, why would the Netherlands take "forty-two months to conduct the initial assessment, instead of the ninety days foreseen in the EC's approval procedures" if this was not to resolve scientific or technical issues?

77. It is reasonable to infer from the surrounding circumstances, that The Netherlands, with the knowledge that there was a *moratorium* in place and that the speed of its review would therefore have little impact upon the eventual date of approval, instead took the extended time to request information from the notifier in an effort to upgrade the dossier to the anticipated new information requirements (especially the detection method) of *Directive 2001/18*. Rather than being an active participant in the *moratorium*, it is reasonable to conclude that The Netherlands was placed in the position of having to accept it and to act or react, as the case may be. It would have been futile for The Netherlands to have issued its favourable report and circulated the dossier to the Community level prior to the entry into force of the *Directive 2001/18* (October 2002) because the EC Member States, *qua* Regulatory Committee, would, in the light of the *moratorium*, have simply stalled the application.

190. With reference to Greece's safeguard measure, Canada refers to this measure as an "import ban" (Canada's first written submission, para. 114). Are import bans subject to Article 2.1 of the TBT Agreement?

78. No. The language of Article 2.1 of the *TBT Agreement*, particularly the reference to "products imported from the territory of any Member...", indicates that this provision is intended to

³⁸ Opinion of the Scientific Committee on Plants on the Submission for placing on the market of genetically modified insect resistant and glufosinate ammonium tolerant (Bt-11) maize for cultivation. (Exhibit CDA-35-H).

³⁹ Expertise Report of the Group of Experts Mandated by the Biosafety Advisory Council, Exhibit EC-63 – attachment 167, p.18, Section 3.8.2 "Residue Assessment".

operate much like Article III:4 of the GATT 1994. That is, its disciplines apply to measures affecting the product in question once it has entered into the territory of the Member whose measure is being challenged.

79. This is why Canada, in its First Written Submission, does not make a claim that the Greek import ban violates Article 2.1 of the *TBT Agreement*.⁴⁰ Notwithstanding the EC's argument in its First Written Submission that "it is clear that the nature and aim of the Greek measures does not differ from those of the other national measures",⁴¹ the explicit wording of the measure itself establishes incontrovertibly that the measure extends solely to a prohibition on the importation of the product in question.⁴²

⁴⁰ Canada First Written Submission, para. 485.

⁴¹ EC First Written Submission, para. 640.

⁴² Greece, Minister of the Environment, Regional Planning and Public Works, *Prohibition on the importation of seeds of a genetically modified rape line bearing the reference number C/UK/95/M5/1*, Government Gazette, 1008, 25 September 1998, pp. 11941-11942 (English translation and Greek original). (Exhibit CDA-72)

ANNEX F-6

COMMENTS BY CANADA ON THE REPLIES OF OTHER PARTIES
 TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF
 THE SECOND SUBSTANTIVE MEETING
 18 MARCH 2005

TABLE OF CASES

Short Form	Full Case Title and Citation
<i>Australia – Salmon</i>	<i>Australia – Measures Affecting the Importation of Salmon</i> , Report of the Appellate Body, WT/DS18/AB/R, adopted 6 November 1998.
<i>EC – Asbestos</i>	<i>European Communities – Measures Affecting the Prohibition of Asbestos and Asbestos-Containing Products</i> , Report of the Appellate Body, WT/DS135/AB/R, adopted 5 April 2001.
<i>Japan – Alcohol II</i>	<i>Japan – Taxes on Alcoholic Beverages</i> , Report of the Appellate Body, WT/DS8/AB/R; WT/DS810/AB/R; WT/DS11/AB/R, adopted 1 November 1996.
<i>Korea – Beef</i>	<i>Korea – Measures Affecting Imports of Fresh, Chilled, and Frozen Beef</i> , Report of the Appellate Body, WT/DS161/AB/R, WT/DS169/AB/R, adopted 10 January 2001.
<i>US – FSC (Article 21.5 – EC)</i>	<i>United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities</i> , Report of the Appellate Body, WT/DS108/AB/RW, adopted 29 January 2002.
<i>US – Section 337</i>	<i>United States – Section 337 of the Tariff Act of 1930</i> , Report of the Panel, BISD 36S/345, adopted 7 November 1989.

Question 119:

1. The EC's assertion that ISPM No. 11 (2004) is not relevant to the *SPS Agreement* is without merit.

2. First, its arguments on timing are both factually misleading and legally wrong. ISPM No. 11 was endorsed by the Interim Commission on Phytosanitary Measures (ICPM) in April 2001. In April 2003, the ICPM endorsed a supplement to ISPM No. 11 on the analysis of environmental risks and agreed that it should be integrated into ISPM No. 11. These resulted in ISPM No. 11 Rev. 1 (*Pest risk analysis for quarantine pests including analysis of environmental risks*). In April 2004, the ICPM endorsed a further supplement to ISPM No. 11 Rev. 1 on pest risk analysis for living modified organisms (LMO) and agreed that this should be integrated into ISPM No. 11 Rev. 1. These supplements are annotated in ISPM No. 11 (2004) with "S1" and "S2" respectively.¹

3. The references to environmental risks in Annex 1 of ISPM No. 11 (2004) were incorporated as a result of the April 2003 supplement. Thus, any attempt by the EC to dismiss references to environmental risks on the basis that these were adopted after the establishment of the Panel is wrong. The suggestion that environmental risks, included by virtue of the April 2003 supplement, are somehow related to the *Cartagena Protocol* is also wrong. It is the April 2004 supplement, not the April 2003 supplement, which deals with LMOs.

¹ "Endorsement", ISPM No. 11 (2004), p. 1 (Exhibit EC-130).

4. Second, the suggestion that the April 2004 supplement is not relevant to the *SPS Agreement* merely because it deals with similar subject matter to the *Cartagena Protocol*, is a recasting of the EC's equally unmeritorious earlier argument that GMOs should be dealt with "outside" the WTO Agreement because they have their own "special agreement", the *Cartagena Protocol*.² By its own terms, the April 2004 supplement concerns those LMOs that "may present a phytosanitary risk and therefore warrant a PRA [pest risk analysis]."³ The April 2004 supplement identifies the specific types of risks to plant life that may arise from LMOs that may constitute "pests".

5. Third, the EC's arguments with respect to the legal relevance of ISPM No. 11, including the April 2004 supplement are equally flawed. The complainants are not arguing that the definitions in ISPM No. 11 are legally dispositive of the interpretation of terms in the *SPS Agreement*. However, given the fact that the *SPS Agreement* refers specifically to "international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention", it is illogical and contrary to the object and purpose of the *SPS Agreement* to dismiss such standards, guidelines and recommendations simply on the basis that one party (the EC) does not like what they say. As Canada has demonstrated, ISPM No. 11 (2004) may be considered by the Panel as a supplementary means of interpretation for terms in the *SPS Agreement*.⁴

6. Fourth, Canada has addressed the EC's attempts to extract "environmental risks" from the *SPS Agreement* in paragraphs 52 to 67 of Canada's Third Written Submission. Suffice to say, the *SPS Agreement* was intended to discipline a specific sub-set of "environmental" measures, namely those applied to protect animal (including wild fauna), plant (including wild flora) and human life or health from risks arising from pests and diseases and those applied to prevent or limit other damage from pests. To claim that these measures are not "environmental" because the term is not used is semantics. While it may be true that "measures for environmental protection, *per se*" are not necessarily SPS measures (*e.g.* pollution abatement, emissions control, trans-boundary movement of hazardous wastes etc.), it cannot be credibly argued that measures to protect certain components of the environment (plants and animals, defined broadly) from the entry, establishment and spread of pests and diseases are not SPS measures. ISPM No. 11 (2004) elaborates on the types of risks to plant, animal and human life or health and other damage intended to fall within the scope of the *SPS Agreement*. The fact that such risks are also referred to as environmental risks, because reasonable people would view them as such, does not magically transform them into non-SPS risks.

7. Finally, the EC's efforts to conjure up an interpretive rationale based on the negotiating history of the *SPS Agreement* is flawed because the materials to which the EC refers do not indicate whether the WTO Members intended for all types of environmental measures to be excluded; indeed, the more plausible reading of those materials is that the WTO Members intended for more general types of environmental measures, such as those relating to air and water quality, waste management, and the like, to be excluded from the coverage of the *SPS Agreement*, but that environmental effects related to SPS-type risks would remain within the scope of that agreement.

Question 120:

8. In relation to paragraphs 13 to 16 of the EC's Answers to Panel Questions (7 March 2005), while economic damage resulting from the presence of pests that affects the quality of plant products (fruits and vegetables) may fall within the scope of "other damage" in Annex A(1)(d), this type of damage does not exhaust the type of damage contemplated under Annex A(1)(d). The EC has presented no principled basis for limiting "other damage" to these situations.

² Canada Second Written Submission, paras. 96-104.

³ *Ibid.*, p. 35.

⁴ Canada Answers to Panel Questions (7 March 2005), para. 4.

9. In relation to the EC's ill-founded arguments relating to "environmental risks" in paragraphs 19 and 20, Canada refers the Panel to Canada's comments with respect to Question 119 at paragraph 6.

Question 121:

10. Canada may have misunderstood the Panel's Question as referring only to relevant risk assessment techniques relating expressly to products of biotechnology. If the Panel's Question relates to generally applicable relevant risk assessment techniques, Canada agrees with the response of the United States to this Question.

11. In relation to paragraph 39 of the EC's Answers to Panel Questions (7 March 2005), Canada has already indicated that it does not agree with the EC that the *Cartagena Protocol* is a "relevant risk assessment technique" developed by a "relevant international organization".⁵ Neither the *Cartagena Protocol* itself, nor the *Convention on Biological Diversity* can be said to be "international organizations". Furthermore, given the fact that the *Cartagena Protocol* is a treaty that has not been ratified by any of the complainants, it is not legally relevant to this case.⁶

Question 122:

12. Canada does not agree with the EC's characterization of the relationship between the conduct of a risk assessment and a WTO Member's chosen level of protection. In responding to the Panel's question, the EC has confused two distinct and separate issues: the level of protection and the presence of a potential risk.

13. In particular, the EC's first reason does not support its argument, and the illustrative example set out in paragraph 48 of the EC's Answers to Panel Questions (7 March 2005) actually demonstrates how the EC misperceives the two issues. In its example, the EC confuses the absence of a risk from the Mediterranean fruit fly with the concept of a low level of protection. In reality, the absence of risk may affect the scope of the risk assessment, but this is not dependent on the level of protection, as such. It arises from a determination that the fruit fly does not pose a risk because in a cold climate there is no risk of establishment and spread.

14. The EC's second "reason" for why the level of protection purportedly can affect the conduct of the risk assessment can only be read as a veiled attack on what the EC has suggested is the complainants' lower level of protection. In reality, the EC is once again confusing the scope of the risk assessment, which relates to the presence of a potential risk, and the chosen level of protection. It is illogical to suppose, as the EC seems to do, that a responsible government will simply ignore potential risks just because its level of protection may be lower than that of another country. Regardless of the level of protection, the risk manager will want complete information about all potential risks, in order to make as informed a decision as is possible in the circumstances, even if the risk management measure ultimately chosen reflects a comparatively high tolerance for risk.

15. The EC's third "reason" betrays a failure on the part of the EC to understand the distinction drawn by the Appellate Body between "scientific uncertainty" and "insufficient scientific evidence". Risk assessment is defined in the *SPS Agreement*, not with reference to the appropriate level of protection, but with reference to an "evaluation of the likelihood of entry, establishment or spread of a pest or disease...according to the sanitary or phytosanitary measures which might be applied" or an

⁵ Canada Answers to Panel Questions (7 March 2005), Question 121, para. 13.

⁶ Canada Second Written Submission, paras. 96 to 104.

"evaluation of the potential for adverse effects on human or animal health". In the hypothetical scenario created by the EC these criteria are not respected. We are not given sufficient details to determine what factors influence the conclusion of the risk assessment with respect to the 5% to 20% variance. Nor are we given any indication as to what risk management measures beyond a simple approval might be available to address the apparent scientific uncertainty faced by both country A and country B. In effect, the EC's scenario is a straw man, intended, not so much to respond to the Panel's question, but to advance the EC's agenda with respect to its contention that the scientific evidence in this dispute, despite the evidence of the scientific experts, is uncertain, incomplete, quickly changing and, of course, very complex.

16. The reality, of course, is that the EC's hypothetical scenario bears no relation to reality. Scientific risk assessments – as mandated and prescribed via detailed requirements – have been performed for all the products in issue. In no case can the EC demonstrate that the risk managers were or are faced with the kind of "dilemma" concocted by the EC in paragraph 53 of its answer to Panel Question 122.

Question 128:

17. In relation to paragraph 56 of the EC's Answers to Panel Questions (7 March 2005), Canada agrees with the EC that the "words 'arising from' indicate a degree of causality" between the product or organism in question and the risk to animal, plant and human life or health. However, the EC is interpreting "arising from" in an overly restrictive manner by limiting the degree of causality to immediate and direct effects. As Canada explained in its answer to Panel Question 187,⁷ the EC cannot have it both ways; it cannot, on the one hand, claim that certain risks are legitimate reasons for stalling the applications of biotech products, while, on the other, claim that these same risks do not "arise from" the biotech product in question. Aside from being inconsistent and illogical, the EC's unduly restrictive interpretative approach to "arising from" finds no support in the text of the *SPS Agreement*, in the light of its context and object and purpose.

18. In paragraph 57 of the EC's Answers to Panel Questions (7 March 2005), the EC treats "biogeochemical cycles" in a vacuum as if they are important in and of themselves. Its equation "if A [GMO] injures B [biogeochemical cycles], A is a "pest" *vis à vis* B" is fundamentally flawed. A would not be a "pest" simply because A adversely affects biogeochemical cycles. Biogeochemical cycles cannot be in and of themselves adversely affected. An effect on biogeochemical cycles may cause adverse effects on plant or animal life or health. In such a case, the B in the EC's equation is plant or animal life or health, not biogeochemical cycles. It does not make sense scientifically to claim that biogeochemical cycles have been adversely affected if plant or animal life or health has not been adversely affected.

19. In any event, as Canada indicated in paragraph 73 of its Third Written Submission, the EC has failed to point to a single instance where a biotech product in question materially affects a relevant biogeochemical cycle. Hypothetical concerns that bear no relationship to the actual risks posed by biotech products in question cannot serve to transform an SPS measure into a non-SPS measure. The EC is simply inventing *ex post ad hoc* excuses to maintain its *moratorium*.

Question 129:

20. Canada has three comments in relation to the EC's answer to Panel Question 129. First, the EC's response that the Regulatory Committee procedure could not have been used to establish harmonized risk assessment objectives and methodology is patently at odds with statements in the

⁷ Canada Answers to Panel Questions (11 March 2005), Question 187, para. 63.

very report relied on by the EC in these proceedings to explain the alleged inadequacies of *Directive 90/220* ("1996 Report").⁸ In the 1996 Report, the Commission stated:

At the same time, while undergoing the procedure for adopting an amended Directive, which will involve a co-decision of the Council and the Parliament, the Commission is committed to making full use of all the tools and flexibility of the current Directive. More specifically, the Commission will intensify the work of the Risk Assessment Group established in the framework of the Committee of the Competent Authorities, so that a common approach to risk assessment objectives and methodology can be adopted as guidance in March 1997.⁹

21. Tellingly, the EC fails to address directly these statements in the 1996 Report (which were quoted in paragraph 61 of Canada's Second Written Submission) when responding to the Panel's question. The EC is taking a selective approach to the facts in order to suit its present purposes.

22. Second, the intent of *Directive 90/220* clearly was to allow for such harmonization beyond the formalistic approach the EC now chooses to describe. The preamble to the *Directive* states, in part, as follows:

Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;...

Whereas it is necessary to establish harmonized procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;...

Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress.

23. It seems odd indeed that the Directive would refer specifically to the necessity to establish harmonized procedures and criteria and not empower the Regulatory Committee to adopt the same.

24. Third, the EC's argument that the Regulatory Committee procedure was "limited to 'adaptation' of Annex II and III" is unconvincing. Annex II and III of *Directive 90/220* set out the information that must be contained in the notification. In addition, the notifier was required to include in the notification "an assessment of any risks for human health and the environment related to the GMOs or a combination of GMOs."¹⁰ Similarly, the new Annex II of *Directive 2001/18* (Principles for the Environmental Risk Assessment) refers to the information that must be included in the environmental risk assessment submitted with the notification.¹¹ Under both *Directives*, the notifier conducts the risk assessment and submits the results of the risk assessment as a part of the notification. Consequently, the EC has simply specified under *Directive 2001/18* the type of information relating to the environmental risk assessment that is required now to be submitted in the

⁸ EC, Commission, *Report on the Review of Directive 90/220/EEC*, Com(96) 630 final (Exhibit CDA-119). See Canada Second Written Submission, paras. 58-61.

⁹ *Ibid.*, p. 11. [emphasis added]

¹⁰ *Directive 90/220*, Art. 11(1).

¹¹ *Directive 2001/18*, Art. 13(2)(b).

notification. This is no different in effect from "adapting" the information requirements specified in Annexes II and III of *Directive 90/220*.

Question 130:

25. The EC's response to Question 130 is without merit. First, the EC is incorrect when it states that the term "food safety" is not used in the *SPS Agreement*. In fact, the term is found in the definition of an SPS measure in Annex A(1), when it states that "Sanitary and phytosanitary measures include...packaging and labelling requirements directly related to food safety" and in Annex A(3)(a), when elaborating on international standards, guidelines and recommendations relevant to the *SPS Agreement*: "for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission." In the face of this explicit language, the EC's assertion that the WTO Members excluded food safety from the scope of the *SPS Agreement* is plainly wrong. Furthermore, it would be illogical to suppose, and therefore cannot be reasonably argued, that the WTO Members included packaging and labelling requirements related to food safety, but not requirements relating to food safety *per se*.

26. Having established that food safety indeed falls squarely within the scope of the *SPS Agreement*, and that allergenicity is a central food safety concern, the conclusion that the term "toxins" can comfortably be read as including allergenicity is a simple matter of logic and the application of the rules of treaty interpretation. Even if the EC's convoluted argument about a "continuum between food quality and food safety" is accurate in principle, its attempt to equate concerns about nutritional composition – *i.e.* whether the consumer is getting enough vitamin C in his or her diet – and allergenicity – *i.e.* whether the consumer will have an anaphylactic reaction to the presence of peanuts, go into a coma and die – must be rejected as comparing "apples and pears".

27. Finally, the EC's suggestion that allergenicity can arise from sources other than food does not vitiate the arguments that allergenicity is a food safety concern, that the *SPS Agreement* includes food safety issues within its ambit, and that the ordinary meaning of "toxins", when read in its context and in the light of the object and purpose of the *SPS Agreement*, should be understood to include allergens, at least in so far as they arise in food, beverages or feedstuffs.

28. As for the allergenicity issues raised by the EC in paragraph 64 of its Answers to Panel Questions (7 March 2005), the EC has failed to present any evidence that such concerns were raised by either the EC Member States or any of the many scientific committees that actually examined the biotech products in issue in this dispute. It seems to Canada that this is yet another of the many hypothetical scenarios conjured up by the EC in an attempt to evade its responsibilities under the *SPS Agreement*.

Question 131:

29. It is questionable whether the EC's suggestion that the term "condition" is limited only to those conditions of use and handling defined by the applicant is correct. However, assuming, for the sake of the argument, that the EC could only impose conditions proposed by the applicant, nothing prevented the EC (the Commission or the Competent Authorities of the Member States) from requesting applicants to amend their applications to contain such conditions. Indeed, this occurred in relation to maize MON 810. The notifier, at the request of the Commission, undertook to develop an insect resistance management strategy. This undertaking was subsequently noted in the approval decision, *Commission Decision 98/294/EC*.¹²

¹² Canada Second Written Submission, para. 55 and Exhibit CDA-81).

Question 132:

30. The EC's assertion in paragraph 72 of its Answers to Panel Questions (7 March 2005) that the Panel experts suggested that "risk assessment of food uses and feed uses are notably different" is not correct. To the contrary, for the products in issue in this dispute, Dr. Nutti stated that if the results of the food safety assessment confirm the safety of the food, these results would be directly relevant to feed safety. In response to a question from the Panel, Dr. Nutti further clarified that she is not aware of any case, for the products at issue in this dispute, where a food that is safe for human consumption was not also determined to be safe for animals. The long line of EC scientific opinions under *Directives 90/220* and *2001/18* that have reviewed food and feed safety support this conclusion.¹³

Question 136:

31. Canada disagrees with the EC's contention that "one cannot, in the context of Article 5.5 of the *SPS Agreement*, meaningfully compare the actions of the European Communities with those of the Member States, given the different ALOPs". The EC is fully responsible under the WTO Agreement for the actions of EC Member States. If individual Member States apply levels of protection that differ from each other, or from the level of protection sought by Community-wide laws, and the situations in which these ALOPs are applied are comparable, the possibility of a violation of Article 5.5 arises. The EC is in violation of its obligations if the application of different ALOPs, whether by the EC as a whole or by its individual Member States, is arbitrary or unjustifiable and results in discrimination or a disguised restriction on international trade.

32. Furthermore, despite the EC's semantic efforts, Article 5.5 does not draw any distinction, whether explicit or implicit, between "provisional" and "definitive" measures, or "provisional approvals" and "unconditional definitive approvals", whatever the EC might have in mind in coining these terms.

33. In any event, the EC's response is entirely abstract; no attempt is made to link the "reasoning" set out by the EC to the facts in this case, or any of the EC Member State national measures. This is consistent with the EC's approach throughout this dispute; as Canada has noted elsewhere,¹⁴ the EC has yet to put forward a cogent argument that links ALOPs, facts, measures and law together with respect to the EC Member State national measures.

Question 137:

34. Once again, the EC engages in a semantic exercise while failing to address the facts. Regardless of whether scientific evidence is changing – and the EC has not demonstrated that relevant scientific evidence was changing in a manner that stood to affect the original multiple risk assessment conducted in relation to the EC Member State national measures – a WTO Member remains obligated to ensure that the application of different ALOPs does not amount to arbitrary or unjustifiable

¹³ See for example Exhibit CDA-35-A, pp. 4 to 5 ("Because virtually no protein is present in the oil extracted from the plants, the risk for human consumption are non-existent. The amounts of PAT present in seed meal fed to animals would be too low to cause even theoretical concern."). Also, see Exhibit CDA-63, pp. 5 to 6 ("These results lead the Committee to conclude that there is no significant risk to human and livestock following ingestion of the GM seeds...In food of animal origin derived from livestock animals fed with feedstuffs after the application of glufosinate herbicide in tolerant rape, no residues above the limit of determination can be expected...Compositional analysis on seed harvested from trials at a number of locations within Canada in several successive years provided data on oil content, fatty acid composition and glucosinolate levels. Those for the seed from the genetically modified plants fall within the range for non-GM control varieties.")

¹⁴ Canada Second Oral Statement, para. 66.

distinctions in comparable situations, where such distinctions give rise to discrimination or a disguised restriction on international trade.

35. In implying that Canada is arguing that an ALOP, once established, is frozen in time, the EC is misleading the Panel as to the real issues in this dispute. The fact remains that the EC Member States are applying different ALOPs to comparable situations. Canada has already demonstrated this with reference to actual facts and measures.¹⁵ The distinctions being made in this respect are arbitrary and unjustifiable, and they give rise to discrimination or a disguised restriction on international trade.

36. Furthermore, the EC's argument that "every product is different, and every product needs to be considered on its own merits", is absurd. It is both factually inaccurate and would, if heeded, render Article 5.5 meaningless as no comparison would ever be possible. It is also completely contrary to the jurisprudence established by the Appellate Body in *Australia – Salmon*.¹⁶

Question 139:

37. In paragraphs 86 to 88 of the EC's Answers to Panel Questions (7 March 2005), the EC suggests that the Commission would not have known of EC Member State concerns prior to the submission of the draft measure to the Regulatory Committee, and that submitting the draft measure was the only way to gauge those concerns. This is patently false. EC Member States' concerns were typically raised once the Competent Authority's favourable assessment had been circulated at the Community-level. In order to evaluate the legitimacy of these concerns, the Commission typically would seek the advice of the relevant Community-level scientific committee. Only after the scientific committee rendered its favourable opinion would the Commission submit draft measures to the Regulatory Committee. To suggest, as the EC does, that prior to the submission of the draft measure a full airing of the Member State concerns had not taken place is again playing fast and loose with the facts. In all relevant cases, the Commission failed to call for a formal vote as it was apparent to the Commission that the qualified majority necessary to support the measure could not be mustered because of the *moratorium*.

38. In short, the EC's suggestion that only by submitting draft measures to the Regulatory Committee could the Commission find out whether the Member States had outstanding concerns is patently inconsistent with the facts and contradicts the EC's own statements that "...in the Regulatory Committees the Commission and the Member States discuss the applications at length, e.g. present questions and answers" found in paragraph 88 of its Answers to Panel Questions (7 March 2005).

Question 141:

39. In addition to what follows, Canada refers the Panel to paragraphs 152 to 159 and 249 to 252 of Canada's First Written Submission, which establish that the *moratorium* is an SPS measure and that it is subject to Article 7 and Annex B of the *SPS Agreement*.

40. The EC's response to this question misses the point of Canada's argument. The *moratorium* is "applicable generally" in that it suspends all final decision-making under the EC's approval procedure. This is not a question of an "administrative decision in a specific case" but of the procedure not being allowed to function as designed. It is not, as the EC asserts, a measure that is "adopted at the end of a specific administrative procedure", nor does it represent "the outcome of a specific approval procedure in relation to a specific product". It is the adoption (more about this word later) of a measure of general application that affects all products subject to the procedure. The *moratorium* is

¹⁵ Canada First Written Submission, paras. 412-42.

¹⁶ Report of the Appellate Body, paras. 139-178.

therefore a "sanitary [or] phytosanitary regulation[]" and the EC's failure to publish it promptly is a violation of Article 7 and Annex B(1).

41. In regard to paragraphs 94 to 97 of the EC's Answers to Panel Questions (7 March 2005), Canada simply observes that, notwithstanding the EC's somewhat intemperate attack on the wording of the Panel's question, it cannot disguise or detract from the essential facts that Canada has already established. A *moratorium* was not only "adopted", it has had the effect of halting approvals of biotech products since October 1998. Whether the measure was adopted *de facto* or *de jure* is really beside the point, just as it is beside the point what EC law requires in the way of recording such measures. The EC cites Orwell in its efforts to evade this obvious point.¹⁷ It might better have invoked Kafka as the inspiration for its strategy of surreal obfuscation in this case.

Question 142:

42. Although Canada has little difficulty, in principle, with the EC's depiction of the distinction between principles and evidence, the digression in paragraph 99 of the EC's answer to Panel Question 142 misrepresents both the facts and the legal position of Canada.

43. Contrary to the EC's assertions, the evidence has revealed that, in the case of the EC Member State national measures – the only measures for which the EC has invoked Article 5.7 – the scientific evidence was more than sufficient to complete a risk assessment, and that the alleged concerns noted by the EC in paragraph 99 were not a relevant factor. To imply, as the EC does, that there was little or no scientific evidence, and that scientific principles were irrelevant, is to distort utterly the factual situation in relation to these products.

44. Furthermore, the EC's suggestion that potential risks to biogeochemical cycles were an overriding concern in the EC is simply a flight of fancy. There is in fact no evidence to suggest that any of the biotech products in question affect biogeochemical cycles in a manner that adversely affects plant or animal life or health.¹⁸ Finally, even if such evidence existed, the risk could only arise in the case of products approved for cultivation. This is only a fraction of the product applications currently suspended in the EC's approvals process.

Question 144:

45. The EC avoids answering the Panel's Question by discussing products that have been notified under the simplified procedure of Article 5 under *Regulation 258/97* (e.g. GT-73). This misses the point entirely and is yet a further attempt by the EC to avoid addressing the pertinent issues in this dispute by focussing on issues that are at best marginally relevant. Furthermore, the EC is incorrect to characterize these products as having been "approved" under the Community legislation. The EC knows full well that these products were assessed only at the individual EC Member State level, that an opinion was rendered as to whether they met the criteria for substantial equivalence, and that this fact was notified to the other EC Member States through the European Commission.

Question 152:

46. The EC's answer to Panel Question 152 actually confirms Canada's assertion that the Rapporteur had merely re-requested information that it had previously received from the applicant. Specifically, the EC admits that the "blots from the three reports" had already been transmitted to the

¹⁷ EC Answers to Panel Questions (7 March 2005), para. 97.

¹⁸ See Canada Answers to Panel Questions (7 March 2005), Question 148, paras. 68-70. Also see Canada's answer to Panel Question 128, above.

lead CA. Moreover, the EC admits that the working document submitted by the notifier on 17 May 2000 "contained information submitted over the past two years".¹⁹ Indeed, the working document was "taking into account all the supplemental information submitted to the Dutch Competent Authority in the last two years"²⁰ and consolidating that information for the convenience of the Dutch authorities. In the light of the prolonged delays caused by the *moratorium*, one can hardly expect a notifier to simply sit on its hands and do nothing.

Question 154:

47. The EC's response to this question indicates that it cannot justify delays resulting from the "need" for new legislation. Whether or not the EC's traceability and labelling legislation, *per se*, conforms to the EC's WTO obligations has yet to be determined and is not an issue in this case. The fact that the complainants have not challenged the EC's traceability and labelling legislation (which Canada notes only entered into force in April 2004, well after the Panel was established) or co-existence legislation (which has not even been proposed) is irrelevant and does not imply that delays caused by the imposition of a *moratorium* pending the adoption of such legislation are justified under Annex C(1)(a) of the *SPS Agreement*.

Question 158:

48. Canada refers the Panel to paragraphs 189 to 193 of Canada's Second Written Submission, where it demonstrates why the refusal of France to issue the letters of consent for oilseed rape Ms1xRf1 and Ms1xRf2 gives rise to a violation of the EC's obligations under the *SPS Agreement*.

49. The obvious answer to this question is that neither product has been marketed in the EC because neither product received final approval from the sponsoring EC Member State. Under *Directive 90/220*, a product could not be marketed unless it had received the written consent from the sponsoring Member State. Article 11(5) of *Directive 90/220* specified that "the notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13...". Article 13(4) states, in turn, that "...the competent authority shall give consent in writing to the notification so that the product may be placed on the market ...".²¹ In other words, the issuance of the written consent by the sponsoring Member State competent authority was a legal condition precedent to the product being marketed.

50. The proposition that Articles 11(5) and 13(4) of *Directive 90/220* have a legal effect is further supported by the fact that the European Commission issued reasoned opinions to France in relation to its refusal to issue the letters of consent – a necessary precursor under EC law to the Commission bringing legal action against a Member State that has breached its legal obligations – in 1999.²² If the provision in the EC legislation requiring the sponsoring Member State to issue a letter of consent had no legal effect, there would be no need nor indeed a basis for the issuance of reasoned opinions by the European Commission.

Question 159:

51. Canada has no comment other than to observe that it is curious that the EC seems better informed about the status of the transgenic varieties in other jurisdictions than in its own.

¹⁹ EC Answers to Panel Questions (7 March 2005), para. 106 and 107.

²⁰ Exhibit EC-70 – attachment 21.

²¹ Emphasis added.

²² Exhibit CDA-52.

Question 160:

52. Canada appreciates the EC's effort to clarify the legal status of Italy's Decree banning the use of maize MON809, MON810, T25 and Bt11. However, Exhibit EC-166 is, in Canada's view, less than satisfactory as confirmation of that legal status.

53. If, in fact, the Decree has been repealed, as the letter in Exhibit EC-166 indicates, the EC should provide the Panel with a copy of the Italian legislative instrument repealing it. If the ruling by the Regional Administrative Court of Lazio had the effect of rendering the Decree null and void, independently of any action by the Italian government, a translated copy of the court ruling should be submitted to the Panel and the parties, and, if necessary, an explanation of how Italian law operates in this respect, including confirmation that the ruling has not been, and will not be, appealed by the Italian government.

Question 161:

54. Canada notes that the EC response to Question 161 is incomplete. The EC states that the EFSA evaluation of Ms8xRf3 began as of 10 January 2005. Although EFSA received the Commission's request for an evaluation on 11 January 2005, the request is still marked "registration not yet completed."²³ Consequently, the EFSA evaluation has not yet started. Not surprisingly, the EC fails to provide any explanation as to the reason for the delay or offer any explanation for why it took six months after receiving the last of the Member States' objections for the Commission to request EFSA to review the dossier.²⁴

Question 162:

55. Canada notes that, even at this late stage of the proceedings, the EC remains unable – independently of the EC Member State national measures – to articulate the specific level of protection being applied by its respective Member States. Furthermore, Canada disagrees with the EC's vague assertion that it is clear from the measures that they "seek to secure a high level of protection". If anything is clear from the measures – which amount to complete bans on these products – it is that they aim for an acceptable level of risk that is tantamount to zero.

Question 163:

56. Canada has maintained since the outset of these proceedings that the EC has violated Article 5.5 of the *SPS Agreement* by adopting different appropriate levels of protection in different situations, namely in respect of pending biotech applications subject to the *moratorium* and novel non-biotech products (such as herbicide-tolerant crops developed through mutagenesis).²⁵ However, the source of the difference in the appropriate level of protection is not the existence of an approval regime for biotech products, *per se*, but the fact that the EC, by adopting and maintaining a *moratorium*, has effectively prevented the approval procedure from functioning. In the light of the evidence of the experts concerning the comparability of the risks of these two groups of products, the EC's superficial attempt at avoiding this issue by suggesting that it is outside the terms of reference of this Panel is truly a last desperate attempt to address a losing argument.

²³ EFSA, Register of Requested Opinions, EFSA-Q-2005-005, http://www.efsa.eu.int/register/qr_dateofreceipt_12_en.html.

²⁴ According to the EC Chronology for Ms8xRf3, the last comment received by a Member State was received from Italy on June 22, 2004.

²⁵ Canada First Written Submission, paras. 209-210.

Question 164:

57. The EC responds to Question 164 by claiming that the legal principle that legal acts need to be reasoned does not apply to the Regulatory Committee because it is an auxiliary body "that is merely involved in preparing such an act". The argument appears to be that because no final decision or "acts that have (external) legal effect" have been adopted, the obligation to explain why the institution disregarded the opinion of the scientific committee does not crystallize. This argument parallels the EC's argument that it has not violated Article 5.1 of the *SPS Agreement* because the risk assessment process has yet to be completed. In other words, so long as the EC can prolong the approval process (even indefinitely) without taking a final decision, the EC should be able to circumvent its legal obligations. At least with respect to the EC's WTO obligations, this position is without merit.

58. Canada notes that, in responding to this question, the EC attempts to downplay the role of the Regulatory Committee. The EC relies on a formalistic distinction between the EC Member State and Commission representatives sitting *qua* Regulatory Committee, and the Regulatory Committee itself in suggesting that regulatory committees do not themselves have any power to seek further information. This is little more than semantics. Whether a request for additional information comes from a Member State, the Commission or the formal entity referred to as the Regulatory Committee is immaterial for the purposes of this dispute. The unmistakable fact is that the Regulatory Committee stage of the process, whether one refers to this as the Community-level stage or the first step in the Comitology procedure, has been used by the EC Member States and the Commission to effectively stall the approval procedure.

59. Second, the EC's characterization of the role of the Regulatory Committee is at odds with its previous description of its regulatory bodies. For instance, earlier in its Answers to Panel Questions (7 March 2005), the EC states that the "authorization for the product under question is scrutinized by the Regulatory Committee"²⁶ and refers to the fact that the Regulatory Committee "had not only a regulatory but also an advisory role."²⁷ Similarly, in earlier submissions, the EC has repeatedly characterized the activity of the regulatory committees as related to the consideration of risk management measures. By way of example, the EC refers to the fact that "risk management decisions are left to regulatory bodies"²⁸ and states that "[i]n the risk analysis process, it is up to the risk management level (the Commission and the Member States together) to take appropriately into account all the independent risk assessment information and opinions."²⁹ It is clear that the EC is referring to the activity that takes place at the Community level, under the guise of the relevant Regulatory Committee. It is equally clear that blockage of biotech applications, as a result of the *moratorium*, has been most pronounced at the Regulatory Committee stage of the process.

60. Whether or not the EC community institutions are able to circumvent legal obligations under the EC's internal law by merely claiming that the process has yet to be completed has no impact on the EC WTO obligations: the requirement to base its SPS measures on a risk assessment by virtue of Article 5.1 of the *SPS Agreement* and to undertake and complete its approval procedures without undue delay pursuant to Annex C. The EC cannot circumvent these obligations by claiming that its regulatory bodies (*e.g.* Regulatory Committees) were still in the process of considering supposed risk management measures.³⁰

²⁶ EC Answers to Panel Questions (7 March 2005), para. 83.

²⁷ *Ibid*, para. 86.

²⁸ EC Answers to Panel Questions (16 June 2004), para. 12.

²⁹ EC Answers to Panel Questions (16 June 2004), Question 86, para. 240.

³⁰ Canada Third Written Submission, paras. 26-37.

Question 171:

61. Canada has already refuted the EC's arguments set out in paragraphs 57 and 58 of the EC's answer to Panel Question 171. Canada would simply refer the Panel to paragraphs 103 to 112 of its answer to Panel Question 50(a), paragraphs 230 to 256 of its Second Written Submission, and paragraphs 79 to 108 of its Third Written Submission, which demonstrate that: Article 5.7 constitutes an exemption from the requirement in Article 2.2 not to maintain an SPS measure without sufficient scientific evidence; the burden is on the EC, as the party invoking Article 5.7, to demonstrate its applicability for each of the EC Member State national measures; and the EC has not discharged this burden.

Question 172:

62. Canada disagrees with the EC's contention that a bifurcation can be established between Article 8 and Annex C on the one hand, and the rest of the *SPS Agreement* on the other hand, on the basis of whether the SPS measure in question is being "applied" or "developed". If this bifurcation was intended by the WTO Members, they would not have used the term "applied" in Article 2.2.

63. Furthermore, the text of Article 8 does not stop after "the operation of control, inspection and approval procedures". It goes on to extend the obligation to "procedures...for establishing tolerances for contaminants in foods, beverages or feedstuffs" and to require WTO Members to "otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement." Procedures for establishing tolerances for contaminants must be distinguished from procedures to ensure such tolerances are not exceeded. The former would be a normative measure of general application while the latter is the application (or operation) of a control, inspection or approval procedure, yet no distinction is drawn between them for the purposes of either Article 8 or Annex C.

64. In any event, Canada has already explained why the particular facts in this dispute go considerably beyond the scenario envisaged in the Panel's question of short delays in making a decision,³¹ and has demonstrated how the EC's *moratorium* is inconsistent with both Articles 2, 5, 8 and Annex C(1)(a) of the *SPS Agreement*.³²

Question 173:

65. The EC misrepresents Canada's position in paragraph 64 of the EC's response to Question 173. Canada refers the Panel to paragraphs 18 to 23 of Canada's Answers to Panel Questions (11 March 2005), and paragraph 94 of its Answers to Panel Questions (16 June 2004) for an accurate rendition of Canada's position. In those paragraphs, Canada makes it clear that delaying the approval of specific products is only justifiable where a valid risk assessment has revealed the existence of risks for which the existing legislation does not provide risk management measures.

66. In this regard, the EC suggests that because the complainants have not challenged the EC's new legislation, "it must be accepted as is for the purposes of assessing what may be 'undue'".³³ This is entirely beside the point. The issue is not whether the new legislation is in itself consistent with the WTO rules, but whether the EC was justified in suspending its approvals procedure pending the adoption of that legislation.

³¹ Canada Answers to Panel Questions (11 March 2005), paras. 13-17.

³² Canada First Written Submission, Part VI.A and Part VII.A.

³³ EC Answers to Panel Questions (11 March 2005), para. 69.

Question 177:

67. The EC's assertions regarding the issue of whether biotech products and their conventional counterparts are "like products", and whether the EC measures accord less favourable treatment to imported biotech products, do not reflect the jurisprudence on these points.

68. In particular, the EC suggests that because there is different general legislation for biotech products and their conventional counterparts, they cannot be considered like products. The EC also points to the *Cartagena Protocol* as evidence that biotech products and their conventional counterparts are not like products. However, neither criterion is relevant, much less dispositive, of whether biotech products and their conventional counterparts are like products or not.

69. The EC also argues that the Appellate Body has not said that "the competitive relationship in the market place" is the sole criterion for determining likeness, and that one Member of the Appellate Body in the asbestos dispute was of the view that a "purely economic assessment of likeness is not always appropriate".³⁴ However, these remarks have to be weighed against the underlying purpose of Article III of GATT (and, therefore, also Article 2.1 of the *TBT Agreement*), which is "to avoid protectionism in the application of internal ... regulatory measures ...".³⁵

70. The test for whether two products are "like" under Article III:4 has been set out in the jurisprudence.³⁶ Based on that jurisprudence, Canada has demonstrated in its earlier submissions why specific biotech products and their conventional counterparts are like products in the relevant sense.³⁷ The EC has not presented any arguments or evidence, as regards the Appellate Body-mandated test for likeness, to counter Canada's *prima facie* case in this regard.

71. Turning to the specific issue raised by the Panel in its question – less favourable treatment – the EC's arguments and assertions are without merit.

72. The departure point for a determination of whether an imported like product has been accorded less favourable treatment is, as has been noted repeatedly in the jurisprudence, the question of whether the imported and domestically-produced goods enjoy "equality of competitive conditions".³⁸ In *Korea – Beef*, the Appellate Body elaborated on this point, stating that:

A formal difference in treatment between imported and like domestic products is thus neither necessary, nor sufficient, to show a violation of Article III:4. Whether or not imported products are treated "less favourably" than like domestic products should be assessed instead by examining whether a measure modifies the conditions of competition in the relevant market to the detriment of imported products.³⁹

73. Canada does not question the Appellate Body's statement that WTO Members may draw distinctions between products that have been found to be "like" without, for that reason alone, according less favourable treatment to imported products as compared to their domestic counterparts. However, this statement does not alter in any way the basic requirement that WTO Members must offer equality of competitive conditions.

³⁴ EC Answers to Panel Questions (11 March 2005), para. 101.

³⁵ *Japan – Alcohol II*, Report of the Appellate Body, p. 16.

³⁶ *EC-Asbestos*, Report of the Appellate Body, paras. 87-99.

³⁷ Canada First Written Submission, paras. 304-20 and 451-65.

³⁸ *Japan – Alcohol II*, Report of the Appellate Body, pp. 16-17.

³⁹ *Korea – Beef*, Report of the Appellate Body, para. 137.

74. The EC also misunderstands the Appellate Body's comments in paragraph 100 of its report in *EC – Asbestos*. The Appellate Body's use of the word "group" did not signify that "like products" could somehow be broken down into sub-categories. If a finding is made that a biotech product – for example, a Bt maize variety – is "like" conventional maize, then the WTO Member concerned is required to provide equality of competitive opportunities to the Bt maize and the conventional maize, respectively. Thus, the EC's suggestion that the point of comparison must be between imported and domestic biotech products is non-sensical.

75. The Appellate Body has also noted that:

The examination of whether a measure involves "less favourable treatment" of imported products within the meaning of Article III:4...must be grounded in close scrutiny of the "fundamental thrust and effect of the measure itself". This examination cannot rest on simple assertion, but must be founded on a careful analysis of the contested measure and of its implications in the marketplace. At the same time, however, the examination need not be based on the *actual effects* of the contested measure in the market place.⁴⁰

76. In this particular case, careful analysis of the contested measure reveals, both in the case of the *product-specific marketing bans* and the EC Member State national measures, that the effect is to prohibit entirely the biotech products in question from being sold and used in the marketplace. In contrast, the conventional/non-transgenic products continue to enjoy unfettered access to the marketplace. It is difficult to conceive of a situation where "equality of competitive conditions" has been more completely eradicated. Canada is not required to demonstrate the "actual effects" of the EC's measure.

77. Finally, Canada observes that, in *US – Section 337*, the Panel stated that, where differential treatment has been established, "it is incumbent on the [WTO Member] applying differential treatment to show that, in spite of such differences, the no less favourable treatment standard of Article III:4 is met".⁴¹ This suggests that the initial burden is on the complaining party to establish differential treatment. Once differential treatment has been shown, the burden shifts to the responding party to demonstrate that the differential treatment does not result in less favourable treatment. In the specific circumstances of this dispute, Canada has indeed demonstrated differential treatment. In contrast, the EC has not met its burden of demonstrating that the differential treatment has not resulted in less favourable treatment. It has not because it cannot.

Question 198:

78. In paragraph 37 of Canada's Second Oral Statement, Canada was referring to concerns raised by EC Member States such as the following raised by the Belgian Group of experts: "[o]ne can only speculate on the effects in the long-term and on the effects of a large-scale cultivation of the GM-herbicide tolerant crops."⁴² The experts appear to assume that the cultivation of GM-herbicide tolerant crops will result in "cleaner" fields, that is to say, fields with fewer weeds. Whether this is true depends on the herbicide to which the plant is tolerant as well as, critically, the application of the herbicide. Thus, the source of the alleged concerns about farmland biodiversity results from better weed control associated with GMHT crops. Obviously, if the extent of GMHT cropping was limited to a smaller scale, the putative impact on farmland biodiversity would be less pronounced. In any event, the EC avoids the question of whether or not a smaller and progressive introduction of the

⁴⁰ *US – FSC (Article 21.5 – EC)*, para. 215.

⁴¹ *US – Section 337*, para. 5.11.

⁴² Exhibit EC-63 – attachment 166, p. 14.

biotech crop is a feasible option and conspicuously avoids discussing the successful examples cited in paragraph 37 of Canada's Second Oral Statement.

Question 199:

79. The EC's response to Question 199 reveals yet again just how "inconsistent", to use Dr. Squire's term, the EC has been in addressing its concerns about "farmland biodiversity."

80. The EC's attempt in paragraph 110 to complicate the issue of farmland biodiversity in the context of GMHT cropping is misplaced. The EC seeks to obscure the fact that, when stripped of its jargon, the putative impact on farmland biodiversity from herbicide-tolerant crops is related to more effective in-crop weed control.⁴³ Whatever other concerns the EC may have about the impact of modern agriculture on farmland biodiversity (*e.g.* agricultural intensification, crop specialization and monoculture, increased drainage of wetlands, elimination of non-farming habitats etc.), these have nothing to do with GMHT crops and cannot be used to colour this issue.

81. In paragraphs 111 and 112, the EC yet again seeks to uproot biotech crops from the broader agricultural context. The EC offers no factual support for its assertion that limiting "the rate of use of the herbicide, while achieving an acceptable level of efficacy, would in practice be as ineffective as a voluntary measure. Indeed, such requirements would be extremely difficult to enforce or let alone police." The EC completely fails to explain why conditions imposed on the use of herbicides in conjunction with biotech HT crops would be any more difficult to enforce than conditions imposed on the literally hundreds of other herbicide uses approved in the EC, including the use of herbicides with non-biotech herbicide-tolerant crops developed through mutagenesis. For instance, in the UK, over 550 pesticide products are approved for use with oilseed rape alone.⁴⁴ Unsubstantiated assertions are not sufficient to meet the EC's burden of proof in the face of the *prima facie* case that Canada has established.

82. If protecting farmland biodiversity by requiring farmers to leave more in-crop weeds was in fact a genuine policy objective (the EC's selective application of this concern to biotech HT crops, and nothing else, suggests that it is not), the assertion that measures adopted to achieve this objective would be more difficult to enforce for herbicide use in conjunction with biotech HT crops than with any other herbicide use is groundless. Yet again, the EC advances unsupported assertions in an effort to explain away glaring inconsistencies in the manner in which it treats biotech crops and all other forms of agricultural practice.

83. Indeed, contrary to the EC assertion, requiring farmers to apply herbicides in a manner that leaves more weeds in the field has been recognized as a plausible option by scientists involved in the UK FSE:

If the environmental disbenefits of very clean fields are in future judged to be unacceptable in Britain, then additional management practices, such as band spraying (Dewar et al. 2003) or leaving unsprayed strips along field margins, could be used to

⁴³ See, for example, Exhibit EC-38, p. 5 ("The researchers confirmed that the more weeds there are in a field, the more insects there are."; "The researchers think that conventional beet and spring rape fields were richer in wildlife than their GM counterparts because the broad-spectrum herbicides were more effective on weeds than the specific herbicides used on the conventional crops.")

⁴⁴ See Pesticide Safety Directorate Database - Pesticides Register Database (Crop:oilseed rape (<https://secure.pesticides.gov.uk/pestreg/ProdSearch.asp>)).

reduce the negative impacts of cleanliness. The possibilities for mitigation are numerous, but are beyond the scope of this paper.⁴⁵

84. The EC's arguments should be seen for what they are – a convenient pretext for continuing the *moratorium* and *product-specific marketing bans*.

⁴⁵ Heard, M.S., C. Hawes, G.T. Champion, et al., *Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. I. Effects on abundance and diversity*. Phil. Trans. R. Soc. Lond. B (2003) 1819-1832, p. 1831. (Exhibit EC-63 – attachment 154). [emphasis added]